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#### INTRODUCTION AND SUMMARY

- 1. On May 23, 2022, Plaintiff filed her first amended complaint in this case styled Michele Brown, an individual v. Zeltiq Aesthetics, Inc., a Delaware Corporation; Orange Twist LLC, a Nevada Limited Liability Company; DOES 1 through 10, inclusive; ROE Corporations 11 through 20, inclusive; and ABC Limited Liability Companies 21 through 30, inclusive, in the Eighth Judicial District Court in Clark County, Nevada.
- 2. In accordance with 28 U.S.C. § 1446(a), a true and correct copy of all process, pleadings, and orders in the state-court file is attached as **Ex. 1**.
- 3. In the complaint, Plaintiff alleges she underwent treatment with Zeltiq's CoolSculpting device in July 2019 at Defendant Orange Twist, LLC's practice in Las Vegas, Nevada. FAC ¶¶ 132–133 attached hereto as Ex. 1.
- 4. Plaintiff alleges she experienced a warned-of side effect with the CoolSculpting procedure called paradoxical hyperplasia ("PH"), saw multiple healthcare providers to diagnose the condition, and ultimately underwent liposuction and platysmaplasty. *Id.* ¶¶ 131–153. Plaintiff alleges she has been recommended for "additional surgical procedures including a second liposuction and a full face and neck lift" as a result of her treatment with CoolSculpting.
- 5. Plaintiff brings a professional negligence claim against Orange Twist, LLC ("Orange Twist"), who she alleges provided her CoolSculpting treatment, a products liability claim against Zeltiq, and claims against both defendants under the Nevada Deceptive Trade Practices Act, misrepresentation, and concealment. *Id.* ¶¶ 168–263.
- 6. Plaintiff seeks to recover for past and future medical expenses, "physical injury, pain, suffering, permanent disfigurement, and extreme and severe mental anguish and emotional distress." *See, e.g., Id.* ¶¶ 201–05.

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#### **GROUNDS FOR REMOVAL**

- Removal is proper because this Court has original subject-matter jurisdiction under I. 28 U.S.C. § 1332(a).
- 7. This Court has diversity jurisdiction under 28 U.S.C. § 1332(a) because this is a civil action between citizens of different states in which the amount in controversy exceeds \$75,000.00, exclusive of interest and costs.
  - A. Complete diversity of citizenship exists between Plaintiff and Defendants.
  - 8. Plaintiff is a citizen of Nevada. FAC ¶ 4.
- 9. Zeltiq is and was at the time Plaintiff filed this lawsuit a citizen of the states of Delaware and Illinois because it is incorporated under the laws of the State of Delaware and has its principal place of business in Illinois. 28 U.S.C. § 1332(c)(1).
- 10. Defendant Orange Twist, LLC is a limited liability company. FAC ¶ 6. For purposes of diversity jurisdiction, "a limited liability company is a citizen of every state of which its owners/members are citizens." 3123 SMB LLC v. Horn, 880 F.3d 461, 465 (9th Cir. 2018) (quoting Johnson v. Columbia Props. Anchorage LP, 437, F.3d 894, 899 (9th Cir. 2006)).
- 11. Upon information and belief, Defendant Orange Twist's members are citizens of the state of California. See Ex. 2, Cal. Sec'y of State, Statement of Information for Orange Twist LLC (listing California resident as member); Ex. 3, Nev. Sec'y of State, Filing History for Orange Twist LLC (listing California residents as managers and officers).
- 12: For purposes of removal, "the citizenship of defendants sued under fictitious names shall be disregarded." 28 U.S.C. § 1441(b)(1). Thus, the citizenship of fictitious Defendants "DOES 1 through 10," "ROE Corporations 11 through 20," and "ABC Limited Liability Companies 21 through 30" is irrelevant to removal.

### B. The amount-in-controversy requirement is satisfied.

13. Where state practice does not permit a demand for a specific sum or permits recovery of damages in the excess of the amount demanded, the notice of removal may assert the amount in controversy. 28 U.S.C. §1446(c)(2). Nevada law prohibits a plaintiff from demanding in her complaint a numerical dollar amount in excess of \$10,000. Nev. R. Civ. P. 8(a).

- 14. Under 28 U.S.C. § 1446(a), a removing defendant need only include in its notice of removal "a short and plain statement of the grounds for removal." 28 U.S.C. § 1446(a). The Supreme Court has explained that "by borrowing the familiar 'short and plaint statement' standard" from Rule 8(a) of the Federal Rules of Civil Procedure, Congress "intended to 'simplify the pleading requirements for removal' and to clarify that courts should 'apply the same liberal rules [to removal allegations] that are applied to other matters of pleading." *Dart Cherokee Basin Operating Co. v. Owens*, 574 U.S. 81, 87 (2014) (quoting H.R. Rep. No. 100-889, p. 71 (1988)). The Court held that to satisfy the "short and plain statement" requirement, the removal notice must allege the amount in controversy "plausibly" but "need not contain evidentiary submissions" to support the allegation. *Id.* at 84. In so holding, the Court quoted *Ellenburg v. Spartan Motors Chassis Inc.*, 519 F.3d 192 (4th Cir. 2008), for the proposition that "a removing party's notice of removal need not 'meet a higher pleading standard than the one imposed on a plaintiff in drafting an initial complaint." *Dart Cherokee*, 574 U.S. at 86.
- 15. The amount pleaded by the defendant "should be accepted when not contested by the plaintiff or questioned by the court." *Henson v. Freedom Life Ins. Co. of Am.*, 2021 WL 3216466, at \*3 (D. Nev. July 29, 2021) (quoting *Dart Cherokee*, 574 U.S. at 87). In the event a defendant's amount-in-controversy allegation is questioned, the court must provide the parties with an opportunity to submit evidence and then decide whether the preponderance of the evidence shows that the amount in controversy is met. *See Arias v. Residence Inn by Marriott*, 936 F.3d 920, 924 (9th Cir. 2019).
- 16. It is facially evident from the Complaint that the amount in controversy exceeds \$75,000.00, exclusive of interest and costs. Plaintiff alleges that after her CoolSculpting treatment in July 2019, she saw no less than six different healthcare providers, underwent a liposuction procedure and platysmaplasty, and will likely undergo "additional surgical procedures including a second liposuction procedure and a full face and neck lift." She claims she requires "multiple invasive surgical procedures to correct [her] disfigurement." FAC ¶¶ 135–155. Aside from these claimed past and future medical expenses, Plaintiff seeks to recover for her "disfigurement," "significant life-altering injuries," and "significant pain and suffering." *Id.* ¶¶ 160, 163

- 17. In addition, Plaintiff seeks punitive or exemplary damages, FAC ¶ 225 & p. 33, which are "part of the amount in controversy in a civil action." Gibson v. Chrysler Corp., 261 F.3d 927, 945 (9th Cir. 2001).
- 18. In short, considering the nature of injuries Plaintiff alleges, her request for damages for past and future medical expenses, pain, and permanent disfigurement, it is clear that the amount-in-controversy is met as to each Defendant.

#### II. Zeltiq has met the procedural requirements for removal.

- 19. Zeltiq was first served with a copy of the Complaint on May 31, 2022. Therefore, this removal is timely because it is filed within 30 days after service of the initial pleading. 28 U.S.C. § 1446(b)(1), (b)(2)(B).
- 20. Upon information and belief, Defendant Orange Twist LLC has not been served, as no return of service has been filed. Thus, Orange Twist LLC's consent to removal is not required. 28 U.S.C. § 1446(b)(2)(A).
- 21. The Eighth Judicial District Court in Clark County, Nevada is located within the District of Nevada, 28 U.S.C. § 108, and removal to this Court is proper under 28 U.S.C. § 1441(a) because the District of Nevada embraces the place in which the removed action was pending.
  - 22. No previous application has been made for the relief requested herein.
- 23. Immediately following the filing of this Notice of Removal, Zeltiq will deliver a written notice of filing of this Notice to Plaintiff, as required by 28 U.S.C. § 1446(d). Defendants will also promptly file a copy of this Notice with the Eighth Judicial District Court in Clark County, Nevada, as required by 28 U.S.C. § 1446(d).

### WHEREFORE, Defendants respectfully remove this action from the Eighth Judicial District Court in Clark County, Nevada, San Francisco County, to this Court under 28 U.S.C. § 1441. DATED: June 21, 2022 /s/ Sarai L. Thornton Sarai L. Thornton sthornton@skanemills.com SKANE MILLS LLP 1120 Town Center Dr., Suite 200 Las Vegas, NV 89144 Telephone: (702) 363-2535 Facsimile: (702) 363-2534

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## **EXHIBIT 1**

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ANDRÉA L. VIEIRA, ESQ.

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Attorney for Plaintiff

DISTRICT COURT CLARK COUNTY, NEVADA

MICHELE BROWN, an individual;

Plaintiff,

VS.

ZELTIQ AESTHETICS, INC., a Delaware Corporation; ORANGE TWIST LLC, a Nevada Limited Liability Company; DOES 1 through 10, inclusive; ROE CORPORATIONS 11 through 20, inclusive; and ABC LIMITED LIABILITY COMPANIES 21 through 30, inclusive,

Defendants.

CASE NO.:

A-22-848890-C

DEPT. NO.: I

#### FIRST AMENDED COMPLAINT

Plaintiff, MICHELE BROWN ("Plaintiff"), by and through her counsel of record, Andréa L. Vieira, Esq., of the THE VIEIRA FIRM, and for her causes of action against Defendants, and each of them, hereby complains and alleges as follows:

#### STATEMENT OF JURISDICTION AND VENUE

- 1. The Eighth Judicial District Court has jurisdiction over this action pursuant to Art. VI Sec. 6 of the Nevada Constitution, NRCP 8(a)(4), NRS 13.040, NRS Chapter 41, and NRS 41.130 as the occurrence giving rise to this case took place in Clark County, Nevada and the amount in controversy exceeds \$15,000.00.
- 2. Jurisdiction by this Court is proper over Defendants in this action because each Defendant has done and continues to do business in the State of Nevada, including, but not limited to, providing medical services, and selling harmful products to Nevada residents in violation of

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Nevada laws.

3. Plaintiff, Michele Brown, paid for and received the procedures that are the subject of this litigation including, but not limited to, the CoolSculpting procedures and the diagnostic and corrective medical treatment related thereto, in Clark County, Nevada.

#### **PARTIES**

- 4. Plaintiff is, and at all relevant times was, an individual residing in Clark County, Nevada.
- 5. Upon information and belief, at all times relevant hereto, Defendant, ZELTIQ AESTHETICS, INC. ("ZELTIQ") is a Delware Corporation doing business in the State of Nevada, and is the manufacturer of the CoolSculpting® system which was marketed, sold, and used in Las Vegas, Nevada.
- 6. Upon information and belief, at all times relevant hereto, Defendant ORANGE TWIST LLC ("ORANGE TWIST") is and was a Nevada Limited Liability Company doing business in Clark County, Nevada operating aesthetic treatment shops.
- 7. Upon information and belief, ORANGE TWIST is one of the largest providers of CoolSculpting® treatments, with four CoolSculpting machines per location.
- 8. Upon information and belief, ORANGE TWIST merged with Illuminate Face & Body Bar on or about April 30, 2019, resulting in all Illuminate Face & Body Bar locations being fully branded as OrangeTwist locations on or about July 2019, and making ORANGE TWIST the successor in interest to Illuminate Face & Body Bar.
- 9. Upon information and belief, Illuminte Face & Body Bar was and is fully incorporated into ORANGE TWIST.
- 10. The true names and capacities, whether individual, corporate, associate, governmental or otherwise, of defendants DOES 1 through 10, ROE CORPORATIONS 11 through 20; and ABC LIMITED LIABILITY COMPANIES 21 through 30 ("DOE/ROE/ABC"), are unknown to Plaintiff at this time, whom therefore sues said defendants by such fictitious names. When the true names and capacities of said defendants have been ascertained, Plaintiff will amend this Complaint accordingly.

- 11. Upon information and belief, DOE/ROE/ABC are responsible, negligently, or in some other actionable manner, for the events and happenings hereinafter referred to, and caused injuries and damages proximately thereby to Plaintiff as hereinafter alleged.
- 12. Upon information and belief, DOES/ROES/ABC were involved in the initiation, approval, support or execution of the wrongful acts upon which this litigation is premised, or of similar actions against Plaintiff of which Plaintiff is presently unaware.
- agents, servants, employees, employers, partners, contractors, co-owners and/or joint venturers of each other and their co-defendants, and were acting within the color, purpose and scope of their employment, agency, contract, ownership and/or joint ventures and by reason of such relationships the Defendants, and each of them, are vicariously and jointly and severally responsible for the acts and/or omissions of their co-Defendants. It is understood that DOES/ROES/ABC defendants may include physicians, surgeons, nurses, scrub technicians, certified nursing assistants, estheticians, esthetician assistants, hospitals and/or entities engaged in the business of healthcare and/or cosmetic care and that said entities and/or individuals were the agents, ostensible agents, servants, employees, employers, partners, co-owners and/or joint venturers of each other and their co-defendants, and were acting within the color, purpose and scope of their employment, agency, contract, ownership and/or joint ventures and by reason of such relationships the Defendants, and each of them, are vicariously and jointly and severally responsible for and liable for the acts and/or omissions of their co-Defendants.

## FACTS COMMON TO ALL CAUSES OF ACTION

### Nature of Plaintiff's Claims

- 14. Plaintiff repeats and realleges the allegations contained in the preceding paragraphs as though fully set forth herein.
- 15. This lawsuit and following allegations arise from a popular non-invasive fat reducing medical device called the CoolSculpting® System ("CoolSculpting"), which has the ability to cause permanent deformities to a person's body.
  - 16. CoolSculpting® is a trademark of Zeltiq Aesthetics, Inc., an AbbVie company.

- 17. On or about March 9, 2021, Plaintiff was diagnosed with Paradoxcial Adipose Hyperplasia ("PAH") as a result of the CoolSculpting procedure performed on her at Illuminte Face & Body Bar.
- 18. ZELTIQ advertised and continues to advertise CoolSculpting as a "nonsurgical" procedure intended to reduce stubborn fat bulges "in the areas that bother you most." CoolSculpting promises "up to 20-25% reduction in fat layer thickness after a single session." See <a href="https://www.coolsculpting.com/coolsculpting/">https://www.coolsculpting.com/coolsculpting/</a>
- 19. Upon information and belief, ZELTIQ knew since at least 2011 that the CoolSculpting device can cause consumers to develop PAH, which results in the *opposite effect* of the medical device's advertised purpose. The CoolSculpting device can *permanently* damage the tissue in the area it targets to reduce, creating a deformity on the patient's body *much larger* in size than the original "stubborn fat bulge."
- 20. The PAH condition does not resolve on its own, and unlike regular fat tissue, tissue affected by PAH does not respond to weight loss. Thus, the only method of removing PAH is through invasive surgery.
- 21. Since the device went on the market, ZELTIQ has received thousands of reports of CoolSculpting consumers that have developed PAH after undergoing the CoolSculpting procedure.
- 22. ZELTIQ created "liposuction program" to address the PAH incidents resulting from the CoolSculpting procedure.
- 23. ZELTIQ worked with CoolSculpting providers in regard to liability claims for PAH and together with and through its affiliated company, Allergan Aesthetics, offered to refund patients or pay them for one liposuction procedure to correct the effect of PAH in exchange for a release of liability benefiting the ZELTIQ, its affiliated companies, and the provider. This "liposuction program" mislead consumers to believe that PAH can be successfully corrected with a single liposuction procedure, if required.
- 24. Prior to performing the CoolSculpting procedure on Plaintiff, ORANGE TWIST did not inform Plaintiff about the risk of developing PAH as a nature and consequence of the CoolSculpting procedure.

- 25. Consequently, Plaintiff underwent the CoolScultpting procedure and unknowingly subjected herself to the risk of PAH, which is solely attributed to the CoolSculpting procedure.
- 26. ZELTIQ's conduct was systemic across the nation and resulted in thousands of consumers being affected in the same manner.

#### **Corporate History of CoolSculpting System**

- 27. ZELTIQ either directly or through its agents, servants, and employees, created, designed, manufactured, labeled, marketed, advertised, distributed, and sold its CoolSculpting System medical device to be used on individuals to induce lipolysis (the breaking down of fat cells) in the body.
- 28. On or about April 28, 2017, Allergan PLC and Allergan Inc. acquired Zeltiq Aesthetics, Inc. for the purchase price of \$2.48 billion.
- 29. On or about May 8, 2020, AbbVie, Inc. acquired Allergan PLC, Allergan, Inc., and Zeltiq Aesthetics, Inc. for the purchase price of \$63 billion.

#### **About the CoolSculpting System**

- 30. CoolSculpting is a body contouring procedure that is supposed to work by using a process called Cryolipolysis®, which freezes fat cells and programs them to die over the course of several months.
- 31. The Cryolipolysis® process was developed and patented by Drs. Richard Rox Anderson and Dieter Manstein at Harvard University and Massachusetts General Hospital in the early 2000's. See *Zeltiq Aesthetics, Inc. v. Daron Scherr, M.D. et. al.*, Case No.: 2:15-cv-00186 ¶10.
- 32. ZELTIQ developed a medical device called CoolSculpting System to administer the Cryolipolysis procedure on patients seeking to reduce stubborn fat without surgery.
- 33. The CoolSculpting System device consists of several parts, including the main control unit (the body of the device), the applicators (arms extending from the body), gel pads for the applicators, massage function, consumable cards, liners, pretreatment skin wipes, and securement systems.
- 34. The concept of Cryolipolysis® is based on a theory that fat tissue is more vulnerable to cold temperatures than the skin; therefore, if cold is applied to a person's unwanted fat bulge, the

cold temperature will kill the fat cells and leave the skin intact. The fat cells are not killed immediately but are rather "programmed" to die over time. Persons undergoing the procedure are expected to see "results" 1-3 months after the procedure, as the fat cells wither away in the treatment area.

- 35. CoolSculpting's premise is based on the fact that the human body has a certain number of fat cells that do not change during the course of a person's life. The CoolSculpting device can reduce fat by reducing the number of fat cells through this cold-assisted lipolysis process.
- 36. The U.S. Food and Drug Administration ("FDA") cleared Cryolipolysis® CoolSculpting device for the performance of Cryolipolysis® services to the following areas: upper arm, bra fat, back fat, banana roll (underneath the buttocks), thighs, abdomen, and flank ("love handles"), submental, and submandibular areas.<sup>1</sup>
- 37. The CoolSculpting device is the only medical device in the United States with FDA clearance to offer body contouring services via Cryolipolysis®.
- 38. The CoolSculpting device is a Class II prescription medical device that should only be sold to physicians.
- 39. In order to facilitate Cryolipolysis®, the CoolSculpting device's suction applicators are applied to a person's body and cool the treatment area for 30 to 60 minutes. Each application of the applicator is called a "cycle." A person may undergo multiple cycles in one CoolSculpting session, depending on the size of the area they desire to treat with Cryolipolysis®.
- 40. CoolSculpting is a relatively expensive procedure. An average session of CoolSculpting costs \$2,000 \$4,000, at an average price per cycle (one application of the device) of \$650-\$800. Upon information and belief, Plaintiff received two rounds of Coolsculpting paying between \$700 and \$1,000, per round.

#### **Advertising for CoolSculpting System**

41. ZELTIQ has extensively marketed and promoted its CoolSculpting system directly

<sup>&</sup>lt;sup>1</sup> See DHHS, FDA. Dermal Cooling Pack/Vacuum/Massager, 510(k), K193544: ZELTIQ Coolsculpting System. Indication for Use. Retrieved from <a href="https://www.accessdata.fda.gov/cdrh">https://www.accessdata.fda.gov/cdrh</a> docs/pdf19/K193566,pdf

to the public and continues to do so today.<sup>2</sup>

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<sup>2</sup> See Zeltiq Aesthetics, Inc. Annual 10-K Report.

https://www.sec.gov/Archives/edgar/data/1415336/000162828016012690/zltq-12312015x10k.htm

<sup>3</sup> See <a href="https://www.coolsculpting.com/what-is-coolsculpting/">https://www.coolsculpting.com/what-is-coolsculpting/</a>

<sup>5</sup> See Zeltiq Aesthetics, Inc. (2015). Annual 10-K Report. Page 6/153.

- 42. At all times material, ZELTIO used the same or similar language and messaging throughout its advertisement materials.
- 43. CoolSculpting is advertised and marketed as a non-invasive and surgery-free procedure that is an alternative to liposuction and other fat reducing surgeries.
- CoolSculpting promises to reduce fat up to 20-25% after only one session and 44. promises results in one to three months.
- 45. CoolSculpting claims that the fat reduction after the procedure is "long lasting" and that the device permanently kills the fat cells. It boasts, "Our experts spent years developing the treatment, which features one-of-a-kind technology that quite literally freezes and kills fat cells."<sup>3</sup>
- 46. The CoolSculpting System has received substantial press coverage in the national media since its clearance by the FDA for non-invasive, cosmetic, body-contouring, including features on television shows such as The Today Show, Good Morning America, The CBS Early Show, The Rachel Ray Show, The Dr. Oz Show, Extra, Nightline, The Doctors, and E! News, and in magazines such as O, Elle, Marie Claire, Allure, Men's Fitness, Town & Country, Elevate, W, and Vie.4
- 47. ZELTIQ operated and still operates a website www.coolsculpting.com where it also advertises CoolSculpting directly to the public and refers prospective patients to CoolSculpting providers in their geographical area.
- 48. In addition to intensely marketing the CoolSculpting device to the general public, ZELTIQ aggressively pursued doctor's offices, medical spas, laser hair removal clinics, and other cosmetic procedure establishments to sell its CoolSculpting System device and induce them to add CoolSculpting to their list of medical procedures provided to their cosmetic patients.5
  - 49. ZELTIQ spent millions of dollars partnering with individual CoolSculpting

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<sup>&</sup>lt;sup>4</sup> See Zeltiq Aesthetics, Inc. v. Daron Scherr, M.D. et. al., Case. No.: 2:15-cv-00186. ¶15.

providers, paying for local ads that promote the CoolSculpting services at the providers' clinics.

- 50. The CoolSculpting medical device is specifically programmed to function with the use of consumable cards, called "cycles," which CoolSculpting providers must buy from ZELTIQ to operate the medical device.<sup>6</sup>
- 51. "A cycle is an authorization to perform one procedure to one specific area on the body; [providers] can only perform a treatment if they have purchased a cycle."
- 52. CoolSculpting® net revenues (including both CoolSculpting® Systems/Applicators and Consumables) in the fourth quarter of 2018 were \$81.3 million.8
- 53. ZELTIQ trained providers about on how to increase revenue and CoolSculpting sales by using various sales tactics. ZELTIQ's training materials include sample scripts to use on prospective CoolSculpting patients and describe upselling methods such as having the patients return for a "follow-up appointment" where the provider has an opportunity to sell additional cycles or by pre-selling CoolSculpting packages where the patient pays for multiple cycles in advance for future uses.<sup>9</sup>
- 54. ZELTIQ furnished CoolSculpting providers with advertisement materials directed at CoolSculpting patients, which describe the benefits of the procedure, such as brochures and posters.

#### **Issues with the CoolSculpting System**

- 55. In some cases, the intended injury of the CoolSculpting device triggers the body's wound healing process in response to the cryo-assault and the injured tissue goes into cellular adaptation mode.
- 56. Cellular adaptation is a process in which injured cells try to adapt to an adverse environment by acting abnormally. Cellular adaptation can present itself in various ways

<sup>&</sup>lt;sup>6</sup> See Zeltiq Aesthetics, Inc. (2015). Annual 10-K Report. Page 6/153.

<sup>&</sup>lt;sup>7</sup> See *Id*.

<sup>&</sup>lt;sup>8</sup> See Allergan Reports Fourth Quarter and Full-Year 2018 Financial Results; retrieved from: <a href="https://news.abbvie.com/news/allergan-press-releases/allergan-reports-fourth-quarter-and-full-year-2018-financial-results.htm">https://news.abbvie.com/news/allergan-press-releases/allergan-reports-fourth-quarter-and-full-year-2018-financial-results.htm</a>

<sup>&</sup>lt;sup>9</sup> See Guidelines for CoolSculpting Success. https://docplayer.net/docview/26/9289425/#file=/storage/26/9289425/9289425.pdf

including, hyperplasia – a process in which a cell multiplies, thereby increasing the size of the affected tissue, and hypertrophy – a process in which a cell enlarges caused by an increase in organelles, and structural proteins, also resulting in an increase in the size of the affected tissue.

- 57. Hyperplasia and hypertrophy are the first step of the wound healing process which eventually results in fibrosis or fibroplasia, an irreversible disease of the tissue. Fibrosis is the end result of the body's wound healing process in response to an injury.
- 58. Paradoxical Adipose Hypertrophy ("PAH"), an adverse effect of CoolSculpting, is an example of the body's response to an injury.

#### Paradoxical Adipose Hypertrophy and CoolSculpting Procedures

- 59. At some point in 2011, ZELTIQ became aware that its CoolSculpting System device had the ability to cause patients to develop a condition that results in the opposite effect of the device's advertised purpose a permanent increase in the size of the treated fat bulges.
- 60. Paradoxical Adipose Hyperplasia, also known as "PAH" and referred to as Paradoxical Hyperplasia or "PH" by ZELTIQ is a permanent condition that is developed only as of the result of undergoing Cryolipolysis® via the CoolSculpting device.
- 61. Other than a single report in 2019 of a patient developing a similar condition from a different fat reducing device (or a combination of two devices), PAH has solely been associated with the CoolSculpting device.
- 62. PAH, as seen in CoolSculpting patients, is not known to occur naturally and there have been no such cases documented and verified.
- 63. Thus, with the invention of the CoolSculpting System device and the process of Cryolipolysis®, a new adverse medical condition was created called Paradoxical Hyperplasia.
- 64. PAH causes permanent pathological change to the microstructure of the tissue in the CoolSculpting treatment area, affecting various types of cells, including adipocytes, vascular cells, blood cells, macrophages, endothelial cells, stem cells, and interstitial cells.<sup>10</sup>

<sup>&</sup>lt;sup>10</sup> See Seaman, SA; Tannan, SC; Cao, Y; Peirce, SM; Gampper, TJ. *Paradoxical Adipose Hyperplasia and Cellular Effects After Cryolipolysis: A Case Report. Aesthetic Surgery Journal*. 2015 Nov; Vol. 36(1): NP6-NP13. DOI:10.1093/asj/sjv105; and Stroumza, Nathaniel MD; Gauthier, Nelly MD; Senet, Patricia MD; Moguelet,

- 65. The tissue affected by PAH becomes fibrous and different from regular, untreated tissue resulting in enlarged and sometimes hardened tissue masses that are disfiguring to the body.
- 66. ZELTIQ's internal investigation of the condition revealed that PAH tissue is consistent with fibroplasia, which is fibrosis of the treated tissue.
- 67. Fibroplasia is scarring (fibrosis) of the affected tissue resulting from the body's wound healing process after an injury. It is an irreversible process. To manage the fibroplasia the tissue must be surgically excised.
- 68. ZELTIQ has known that PAH tissue can recur after surgery and in some cases cannot be fully removed.
- 69. PAH is not a simply an enlargement of fat in the treatment area, it is a disease of the tissue that results in a deformation of the body.
- 70. Unlike regular fat tissue, PAH does not resolve on its own. Once a person develops PAH after CoolSculpting, the affected tissue does not react the same as regular fat to weight loss. No matter how much weight a person loses after developing PAH, the area affected by PAH will never get smaller. The deforming effect of PAH remains permanently and can only be removed surgically.
- 71. The visual effect of PAH varies from person to person, and may present differently in a single person, depending on the area of the body affected.
- 72. PAH has a wide range of effects on a person's body. In more fulminant cases, it can present itself as an obvious hardened protruding mass, a soft enlargement of tissue, sagging folds, or as a bulge of tissue in the shape of the CoolSculpting applicator.
- 73. Correcting PAH requires various surgeries. The specific type and number of surgeries depend on multiple factors such as: the extent of tissue damage, the particular area of the body affected, and the outcome of the initial surgery to remove affected tissue.
- 74. The types of reconstructive surgeries and procedures necessary to remove PAH include, but are not limited to: power assisted liposuction, liposculpture, excision, plasty, laser

Philippe MD; Nail Barthlemy, Raphael MD; Atlan, Michael MD. *Paradoxical Adipose Hypertrophy (PAH) After Cryolipolysis*. Aesthetic Surgery Journal. 2018; Vol 38(4): 411-417, 415. DOI: 10.1093/asj/sjx159.

 treatment to remove surgery scars.

- 75. Because PAH changes the character of the subcutaneous tissue, removing the fat tissue with liposuction is a difficult process. The affected tissue becomes lumpy, fibrous, and scarlike, which requires the surgeon to use more invasive and aggressive methods of removing the PAH tissue, resulting in longer recovery time and unpredictable results.
- 76. Even with surgeries, a full reconstruction of the affected area is not guaranteed, and the long-term consequences of developing PAH are still unknown.
- 77. A person with PAH is at risk for future health problems, including the return of the deformity years after surgery.
- 78. A person suffering from PAH either has to live with it forever or try to remove it through plastic surgery. Surgical interventions to alleviate the condition require general anesthesia and involve aesthetic and health risks, including death.
  - 79. At this time, the only known prevention for PAH is abstinence from CoolSculpting.

    <u>Awareness of the Risk of PAH and CoolSculpting</u>
- 80. Soon after the CoolSculpting device went on the market, ZELTIQ received multiple reports of patients developing "firm bulges" and fat tissue "increases" in the treatment area after undergoing Cryolipolysis® with the CoolSculpting device.
- 81. Since 2011, ZELTIQ frequently and consistently received reports of consumers developing PAH after CoolSculpting.
- 82. In 2012, ZELTIQ investigated the observed phenomenon and realized that the CoolSculpting device caused irreversible tissue damage that resulted in fibrous and scar-like masses to grow on patients' bodies as a biological response to the trauma caused by CoolSculpting.
- 83. ZELTIQ knew that the disfiguring "bulges" were not healthy fat tissue and required physical removal through surgery to manage.
- 84. Through its investigation, ZELTIQ knew that the CoolSculpting device caused a pathological change to the tissue resulting in fibrosis of the treatment area, which is disfiguring to the body.

- 85. ZELTIQ named the condition "Paradoxical Hyperplasia" a/k/a "PH" and still uses this term to describe the condition. Internally, ZELTIQ has also referred to the condition as "Paradoxical Tissue Hyperplasia."
- 86. In 2012, soon after ZELTIQ discovered that its device has the ability to seriously harm users by causing them to develop PAH after CoolSculpting, the manufacturer commissioned the inventor of the Cryolipolysis® process, R. Rox Anderson, MD and his colleague at Massachusetts General Hospital, Mathew Avram, MD, JD to author a document about the serious and permanent adverse effect, to which ZELTIQ referred to as "the White Paper."
- 87. The White Paper described the condition as follows: "Recently, the manufacturer received eleven separately confirmed reports of patients who developed growth of soft tissue in the treated site(s) over several months following treatment. The soft tissue growth is painless, firm, and visibly enlarged within the treated areas. The enlargement typically started two to three months post treatment, often after the expected reduction in fat, becoming visibly evident at four to five months post treatments. Because the soft tissue enlargement is a rare, unexpected growth of subcutaneous fat tissue, this phenomenon is being termed "paradoxical hyperplasia."
- 88. The White Paper also described very strict criteria for diagnosing PAH, admitted that the side effect is "significant," but also emphasized the rarity of the condition.
- 89. The White Paper also warned, "Patients who are considering undergoing this procedure should be counseled on the possibility of its occurrence, as well as the surgical options available should it occur." *Id.* at 4.
- 90. In 2012, ZELTIQ created its own diagnosis criteria for the condition, which it required CoolSculpting providers to use to diagnose PAH.
- 91. ZELTIQ also knew in 2012 that people can develop PAH in every CoolSculpting treatment area, suffering from multiple fibrous masses that will require surgical removal.
  - 92. ZELTIQ purposely concealed the existence of the White Paper.
  - 93. By 2013, ZELTIQ knew that various types of surgeries had been required to

<sup>11</sup> See https://skinrenu.com.au/wp-content/uploads/2017/03/13.PH-white-paper-FINAL.pdf

remove PAH masses which were not limited to liposuction and included abdominoplasty, excision, and panniculectomy.

- 94. By 2013, ZELTIQ calculated that the incidence rate was 1 in 3,500 patients, but that the number of people developing the condition was increasing exponentially.
- 95. In 2014, Mathew M. Avram, MD, JD, H. Ray Jalian, MD and R. Rox Anderson, MD, among others, published a report stating that the "risk of PAH is approximately 1/20,000."<sup>12</sup> Dr. Anderson and Dr. Avram serve on the Medical Advisory Board for ZELTIQ. Dr. Anderson's employer, Massachusetts General Hospital, receives royalties for licensing intellectual property to ZELTIQ. Dr. Anderson and Dr. Jalian serve as investigators for a clinical trial sponsored by ZELTIQ.
- 96. ZELTIQ knew that out of all adverse events associated with the CoolSculpting device, PAH was the most serious and the most frequently reported.
- 97. ZELTIQ implemented a confirmation system to re-evaluate reports of PAH remotely through its internal "Medical Safety Team" and rejected many reports of PAH, despite medical providers' diagnoses.
- 98. ZELTIQ took an active role in helping CoolSculpting providers diagnose PAH and mitigated the provider's liability exposure by offering the patients money in exchange for a release of liability.
- 99. ZELTIQ guided providers in determining whether the patient should be diagnosed with PAH through its Medical Safety Team or a similar department. ZELTIQ's employees reviewed the patients' medical information and photographs and suggested to the CoolSculpting providers whether a patient should be diagnosed with PAH.
  - 100. ZELTIQ performed its own studies on PAH to determine the cause of the condition.
- 101. ZELTIQ knew that people with PAH must undergo multiple invasive surgeries to remove it, which were not limited to one liposuction.

<sup>&</sup>lt;sup>12</sup> See Jalian, H. R., Avram, M. M., Garibyan, L., Mihm, M. C., & Anderson, R. R. (2014). *Paradoxical adipose hyperplasia after cryolipolysis*. JAMA dermatology, 150(3), 317–319. https://doi.org/10.1001/jamadermatol.2013.8071

- 102. ZELTIQ also knew that persons afflicted with PAH were emotionally distraught to find out that the only way to remove PAH is through invasive surgeries because the draw of the CoolSculpting procedure was to avoid invasive surgery.
- 103. ZELTIQ knew that the surgeries required to remove PAH involved long recoveries, pain, health risks, and financial expenditures. ZELTIQ also knew that some people may not want to undergo invasive surgeries after developing PAH because they are not willing to subject themselves to the risks, pain, inconvenience of recovery, or financial burdens of undergoing the reconstructive procedures, leaving them with the deformity for life.
- 104. ZELTIQ kept a record of the reported incidents of PAH which included important data such as place of treatment, date of treatment, area(s) of the body affected, date PAH was diagnosed, etc. The data gave ZELTIQ information regarding the incidence rate of the condition.
- 105. Though its own investigation of PAH, the adverse event reports, and it's "liposuction program" ZELTIQ had superior knowledge about the extent, severity, and frequency of the condition.
- 106. ZELTIQ manipulated the calculation of the incidence rate and stated inaccurate incidence rate statistics.
- 107. ZELTIQ also instructed its employees to use the words "rare" when referring to PAH in their communications with CoolSculpting providers, the public, and the FDA.
- 2ELTIQ used paid consultants to disseminate inaccurate information regarding the incidence rate of PAH under the guise of scientific publications. The articles emphasized the rarity of the condition and presented false data to support this claim. The paid consultants' articles cited to other publications written by ZELTIQ's paid consultants. ZELTIQ would then cite to these articles when answering questions about PAH to CoolSculpting providers and in its training materials to support its statements that PAH was rare and unlikely to occur.
- 109. ZELTIQ also downplayed the seriousness, permanency, and frequency of PAH to the FDA.
  - 110. For example, on March 14, 2016, ZELTIQ submitted a 510(k) Summary of Safety

and Effectiveness report to the FDA, citing to "literature review" for evidence of adverse events caused by CoolSculpting and reporting that there have been only "6 cases" of "serious adverse events" which include Paradoxical Hyperplasia, but by 2016, ZELTIQ was aware of thousands of PAH reports.

- 111. Likewise, ZELTIQ failed to report all known incidents of PAH to the FDA, despite the FDA's repeated requests to do so.
- 112. PAH is a reportable adverse event due to the permanency and severity of the condition, and because surgical intervention is the only means of resolving the permanently disfiguring condition.
- 113. Since the CoolSculpting device went on the market, ZELTIQ has received thousands of reports of PAH through September 2019. ZELTIQ reported less than 70 to the FDA's public databased MAUDE (Manufacturer and User Facility Device Experience) where information is publicly available.

#### Failure to Warn CoolSculpting Participants

- 114. Although ZELTIQ provided some information regarding PAH, it was misleading and written in such a way as to give the impression that the condition causes a less serious effect and is not likely to occur.
- 115. ZELTIQ creatively chose words that were ambiguous and did not provide enough specificity on the details that were necessary to understand the condition.
- 116. ZELTIQ's "warnings" about PAH were inaccurate in content and ambiguous in the manner of expression. The language used by ZELTIQ did not relay the seriousness, permanency, and frequency of the condition.
- 117. ZELTIQ used salespeople called Practice Development Managers ("PDMs") to provide training to CoolSculpting providers and to inform the providers about PAH.
- 118. ZELTIQ's PDMs were the primary points of contact for CoolSculpting providers to obtain and relay any information regarding the CoolSculpting device. The PDMs provided training on operating the CoolSculpting device, provided information about the device's side effects, gave marketing advice, relayed information from providers to ZELTIQ, and sold

consumable cards to the CoolSculpting providers.

- 119. The PDMs' primary role was to sell ZELTIQ's products to the providers. After the providers purchased the CoolSculpting device, the PDMs' role was to ensure that the providers continued to purchase the consumable cards which are required to operate the CoolSculpting device.
- 120. The same persons that were tasked with providing adverse effect information to CoolSculpting providers were also tasked with selling ZELTIQ's products to them.
- 121. ZELTIQ's policy in regard to PAH was to provide very little information about PAH and wait until a patient develops the condition. Once a CoolSculpting provider notified the ZELTIQ about a potential PAH case.
- 122. ZELTIQ's custom of selectively "confirming" cases of PAH without ever seeing the patient and rejecting medical providers' diagnoses was a systemic company-wide practice designed to minimize the number of PAH incidents reported to the manufacturer and to avoid liability.
- 123. By rejecting cases of PAH, ZELTIQ lowered the incidence rate of its device's adverse effect.
- 124. ZELTIQ controlled the information that was available about PAH by using vague and inadequate language in the labeling materials, incentivizing PDMs to make false verbal statements about PAH, paying consultants to write favorable scholarly publications, by concealing crucial information about PAH, and by downplaying the seriousness and frequency of the adverse events to the FDA.
- 125. Although ZELTIQ received thousands of reports of people developing permanent deformities from PAH after undergoing CoolSculpting, it has never accurately disclosed the number of people injured by its device. ZELTIQ repeatedly used terms such as "rare" and "a small number of people" when referring to PAH and cited to its consultant's articles, to mislead consumers into believing that PAH was not a likely risk of using the CoolSculpting device.
- 126. As the result of ZELTIQ's misrepresentations, CoolSculpting consumers did not understand the severity, permanency, and frequency of PAH.

- 127. CoolSculpting consumers believed that the adverse effect is extremely rare and were under the impression that it was highly unlikely to develop PAH.
- 128. Contrary to the statistics believed by CoolSculpting providers, a recent study suggested that the incidence rate is closer to 1 in 100 or 1%,<sup>13</sup>
- 129. Adverse events with an incidence rate of 1% or higher are considered "common," not rare by the World Health Organization. See Wang, Erica MD; Kaur, Ramanjot MD; Jagdeo, Jared MD. *Commentary on: Paradoxical Adipose Hypertrophy (PAH) After Cryolipolysis*. Aesthetic Surgery Journal. 2018, Vol 38(4): 418-420, 419. DOI: 10.1093/asj/sjx167.
- 130. The actual incidence rate of PAH after CoolSculpting may be closer to 10% when considering the number of CoolSculpting patients that developed mild to moderate tissue increases, which did not present as well-demarcated masses and remain undiagnosed.

#### Plaintiff's Experience with CoolSculpting Treatment

- 131. At all times relevant hereto, ORANGE TWIST, and it unknown and unidentified employees and agents, undertook to treat and care for Plaintiff and impliedly agreed to exercise and use a reasonable degree of care in the diagnosis, care, and treatment of Plaintiff.
- 132. Upon information and belief, on or about July 2019, Plaintiff presented to ORANGE TWIST located at 10000 W Sahara Ave. Ste 107 Las Vegas, NV 89117 to receive CoolSculpting procedures, an FDA approved fat reduction treatment.
- 133. Upon information and belief, on or about July 2019, after checking in at the front desk of ORANGE TWIST, Plaintiff was provided CoolSculpting treatment on areas of her neck.
- 134. Plaintiff was not provided with accurate and adequate information regarding reasonable risks, possible side effects, benefits and purposes of the procedure, and was not provided with any warning or explanation of the risk of such procedures including but not limited to PAH.

<sup>&</sup>lt;sup>13</sup> See Stroumza, Nathaniel MD; Gauthier, Nelly MD; Senet, Patricia MD; Moguelet, Philippe MD; Nail Barthlemy, Raphael MD; Atlan, Michael MD. *Paradoxical Adipose Hypertrophy (PAH) After Cryolipolysis*. Aesthetic Surgery Journal. 2018; Vol 38(4): 411-417, 412. DOI: 10.1093/asj/sjx159; and Vogel, James E. MD, FACS. *Comments on "Paradoxical Adipose Hypertrophy (PAH) After Cryolipolysis*." Aesthetic Surgery Journal. 2018; Vol 38(9): NP135-NP137, 135. DOI: 10.1093/asj/sjy129

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- 135. Following the treatment Plaintiff noticed enlargements and stiff tissues in the areas of her neck where the CoolSculpting treatment was performed but expected that any side effects or such symptoms would dissipate with time.
- After Plaintiff's treatment her chin/neck area was very sore and very hard, and stayed that way even after the thawing time.
- 137. The affected area continued to grow. Plaintiff called ORANGE TWIST to ask about these issues being normal, but was not provided with accurate, truthful, or helpful information.
- 138. On or about February 5, 2020, Plaintiff presented to Cameron Earl, M.D. at Earl Plastic Surgery who noted that Plaintiff had CoolSculpting done on her chin, and it unfortunately increased in size and that she had Kybella done and it also increased in size, and Plaintiff was requesting a surgical consultation.
- 139. Dr. Earl noted Plaintiff's HEENT was notable for submental fat prominence on physical examination but recommended against any surgical intervention and recommended that Plaintiff lose weight at the rate of 1 pound per month and return in one year.
- 140. Dr. Earl also noted that Plaintiff had a previous 2010 cancer diagnosis in the left breast and underwent a left mastectomy and reconstruction.
- On September 29, 2020, Plaintiff presented to Dr. Lanfranchi at The Lanfranchi Center for a free consultation. Dr. Lanfranchi took photos of Plaintiff's face and head area but did not prepare any consultation report.
- On November 3, 2020, Plaintiff presented to Randall Weingarten, M.D. who noted a submental collection of fat and whose impression was that Plaintiff had a lipoma. Dr. Weingarten recommended that Plaintiff consult with a plastic surgeon.
- On November 18, 2020, Plaintiff underwent a CT of the neck with contrast at Desert Radiology, which revealed "Slight asymmetric inferoanterior extension of the left submandibular gland compared to that of the right. Otherwise no definite CT abnormality to correspond with reported palpable anterior neck lump."
  - 144. On December 16, 2020, Plaintiff presented to Anson and Higgins plastic surgery

for a consultation. She was referred to an Ear Nose and Throat ("ENT") specialist and a recommendation for another opinion.

- 145. On January 15, 2021, Plaintiff presented to Jo-Lawrence Bigcas, M.D. at UNLV Otolaryngology Head & Neck Surgery Department who diagnosed Plaintiff with a submental fat deposit and referred her to UNLV Plastics & Reconstructive Surgery for opinion on liposuction/fat removal for chin area.
- 146. On March 9, 2021, Plaintiff presented to Joshua Goldman, M.D. at UNLV Medicine Department of Plastic & Reconstructive Surgery. During this visit Dr. Goldman mentioned to Plaintiff that he had previously read about and had a patient during his subspecialty training with Paradoxcial Adipose Hyperplasia ("PAH") as a result of cryolypolysis and that PAH was potentially the cause of Plaintiff's increased fat in such an isolated area. This was the first time that PAH was mentioned to Plaintiff.
- 147. Dr. Goldman recommended submental incision with direct excision combined with liposuction and possible platysmaplasty.
- 148. On May 5, 2021, Plaintiff underwent a Liposuction and Platysmaplasly with Dr. Goldman at Sahara Surgery Center. Dr. Goldman noted that the cryolipolysis done to her submental area caused hyperplasia of the fat cells in the area causing a contour deformity.
- 149. Dr. Goldman pre-tunneled with a 3mm cannula, commenced liposuction and 50 cc of lipoaspirate was obtained, and made a 4 cm incision and direct excision of some fat centrally and laterally. Dr. Goldman then performed a platysmaplasty by palpating the two medial layers of the platysma with a 2-0 PDS suture.
- 150. On May 11, 2021, Plaintiff returned to Dr. Goldman for a follow up and sutures removal. Dr. Goldman recommended that Plaintiff wear a jaw bra at night.
- 151. On June 22, 2021, Plaintiff presented to Dr. Goldman who noted mild ecchymosis resolved with improved swelling but not complete resolution.
- 152. On August 24, 2021, Plaintiff returned to Dr. Goldman who discussed doing more or smoothing some of her irregularity with filler vs Kybella, and discussed aesthetics of jowls.
  - 153. On November 9, 2021, it was recommended that Plaintiff undergo additional

 surgical procedures including a second liposuction procedure and a full face and neck lift.

- 154. Plaintiff's business is promoted by facial recognition and networking. She became so self-conscious of seeing people that she knows with her disfigured chin, that she began to limit her personal meetings and networking, which began to negatively affect her work.
- 155. CoolSculpting was marketed and sold as a supposed non-evasive, pain free treatment. Instead, Plaintiff now requires multiple invasive surgical procedures to correct the disfigurement.
- 156. Plaintiff is a cancer survivor, was initially concerned with the possibility that the mass she developed was a tumor, a lipoma, or a resurgence of cancer.
- 157. Plaintiff's diagnosis for PAH was delayed because physicians believed that the hard tissue and mass in her neck was a lipoma, a fat mass, or possibly cancer related.
- 158. Plaintiff is a single mother, a business owner, and the sole provider of income for herself and her daughter.
- 159. Plaintiff has been subjected to pain, disfigurement, many expenses, including time away from her family and business, trying to first figure out and now resolve the disfigurement caused by what was supposed to a simple non evasive, pain free cosmetic treatment.
- 160. Plaintiff's life has drastically been changed these past years due to this procedure and she has been irreparably damaged.
- 161. Plaintiff tried to obtain her medical records related to the CoolSculpting treatment provided but ORANGE TWIST was unable or unwilling to locate and provide such medical records.
- 162. Upon information and belief, the medical records have been lost or destroyed by ORANGE TWIST.
- 163. As a result of the Subject Incident, Plaintiff sustained significant life-altering injuries and has and significant pain and suffering.
- 164. As a direct and proximate result of the Subject Incident, Plaintiff was required to obtain medical services and treatment and may, in the future, be required to obtain additional medical services and treatment.

- 165. As a direct and proximate result of the CoolSculpting treatment, Plaintiff has been damaged in an amount in excess of \$15,000.00.
- 166. As a direct and proximate result of the CoolSculpting treatment, Plaintiff has had to retain the services of NETTLES | MORRIS to pursue this action and is entitled to recover costs of suit and reasonable attorney's fees incurred therein.
- 167. Attached hereto as *Exhibit 1* is a declaration of Nitin J. Engineer, M.D., under penalty of perjury, in support of the allegations of Plaintiff's complaint as required by NRS 41A.071 and in compliance with NRS 53.045, the contents of which are hereby adopted and incorporated herein.

## FIRST CAUSE OF ACTION NRS 41A Professional Negligence

(Against Defendant Orange Twist LLC)

- 168. Plaintiff repeats and realleges the allegations contained in the preceding paragraphs and the Declaration of Dr. Engineer attached hereto as *Exhibit 1*, as though fully set forth herein.
- 169. ORANGE TWIST had a duty to exercise reasonable care in its treatment of Plaintiff consistent with the degree of skill and learning possessed by other medical care providers specializing in their respective fields in or around the United States of America.
- 170. ORANGE TWIST's care provided to Plaintiff as described herein and subsequent consultations deviated from, and fell below the standard of care and constitutes professional negligence.
- 171. ORANGE TWIST provided CoolSculpting treatment without adequately investigating or evaluating the safety of the treatment.
- 172. ORANGE TWIST provided CoolSculpting treatment without adequately warning Plaintiff of the risks including but not limited to PAH.
- 173. ORANGE TWIST provided CoolSculpting treatment and then failed to consult with or provide assistance to Plaintiff when she experienced negative side effects.
- 174. ORANGE TWIST provided CoolSculpting treatment and then was not able or willing to provide Plaintiff with her medical records.
  - 175. ORANGE TWIST knowingly and willfully provided CoolSculpting treatment

without obtaining informed consent pursuant to NRS 449A.121 which requires that Plaintiff be adequately informed of (a) the nature and consequences of the procedure; (b) the reasonable risks, possible side effects, benefits and purposes of the procedure; and (c) any alternative procedures available.

- 176. ORANGE TWIST, and its employees and agents, had a duty under NRS 449A.121 to provide Plaintiff with informed consent of the nature and consequences of the procedures; the reasonable risks, possible side effects, benefits and purposes of the procedure; and any alternative procedures available.
- 177. ORANGE TWIST breached its duties owed to Plaintiff by failing to act as a reasonable physician, hospital, or employee of a medical provider, in rendering services, and using skill or knowledge ordinarily used under similar circumstances, providing treatment that was not safe and had known harmful and permanent side effects, and failing to adequately inform Plaintiff and obtain her informed consent.
- 178. ORANGE TWIST's actions and/or omissions, by and through its employees, agents and/or servants, were careless and negligent and were the proximate cause of Plaintiff's injuries and damages.
- 179. Upon information and belief, at all times relevant hereto, Defendants DOES/ROES/ABC were employees/contractors/agents of ORANGE TWIST, and each of them, and were acting within the course and scope of their employment/contract/agency.
- 180. The acts of ORANGE TWIST's staff/employees/agents/contractors as alleged herein, was done by ORANGE TWIST's staff/employees/agents/contractors while acting in the course and scope of their employment for ORANGE TWIST and while under each said ORANGE TWIST's direction and control.
- 181. The liability of Defendants DOES/ROES/ABC and each of them, as the officer/director/manager/staff/employee/contractor/agent of ORANGE TWIST, and each of them, for Plaintiff's injuries and damages as described herein, is fully and wholly imputed to ORANGE TWIST, and each of them, by virtue of its employment/contract/agency of/with ORANGE TWIST and DOES/ROES/ABC pursuant to the doctrine of *respondeat superior*.

- 182. ORANGE TWIST's conduct amounted to a conscious disregard of the health and safety of Plaintiff.
- 183. As a result of ORANGE TWIST's breach of the standard of care, Plaintiff continues to suffer severe pain and suffering, permanent disfigurement, and subjection to the need of future invasive surgical procedures.
- 184. As a proximate result of the negligence of the ORANGE TWIST, Plaintiff has been damaged in an amount in excess of \$15,000.00.
- 185. As a further proximate result of ORANGE TWIST's negligence, Plaintiff suffered permanent injury.
- 186. As a further proximate result of ORANGE TWIST's negligence, Plaintiff, has incurred and will incur economic losses in the future in excess of \$15,000.00.
- 187. As the actual, direct, proximate, and legal result of the acts and omissions of Defendant, Plaintiff has suffered and will continue to suffer significant physical injury, pain, suffering, permanent disfigurement, and extreme and severe mental anguish and emotional distress all to Plaintiff's damage in an amount in excess of \$15,000.00.
- 188. As a direct and proximate result of ORANGE TWIST's negligence, Plaintiff has had to retain the services of THE VIEIRA FIRM to pursue this action and is entitled to recover costs of suit and reasonable attorney's fees incurred therein.

#### SECOND CAUSE OF ACTION

## Negligent Hiring, Training, and Supervision (Against all Defendants)

- 189. Plaintiff repeats and realleges the allegations contained in the preceding paragraphs and the Declaration of Dr. Engineer attached hereto as *Exhibit 1*, as though fully set forth herein.
- 190. Defendants, and each of them, owed Plaintiff a non-delegable duty to exercise due care in the training, oversight, direction, hiring, retention, and control of its employees/agents/contractors.
- 191. Defendants breached this non-delegable duty owed to Plaintiff by hiring employees/agents/contractors that it knew or reasonably should have known were unfit for the duties they were to perform, and/or by failing to provide proper oversight, training, direction,

hiring, retention, and control of or to its employees/agents/contractors responsible for performing these duties.

- 192. Defendants breached the above-referenced duty when they negligently, carelessly, and recklessly hired, trained, supervised, oversaw, directed and/or retained its employees/agents/contractors.
- 193. Defendants, and each of them, and their personnel including their employees/agents/contractors, intentionally acted to cover up the existence and cause of the injuries and conditions described herein, by failing or refusing to investigate, document, and report such conditions.
- 194. Defendants, and each of them, operated their enterprises in a manner in order to decrease expenses and increase revenue. Defendants, and each of them, implemented cost cutting measures, which included failing to adequately train and/or screen existing or incoming staff to ensure they were competent in meeting the needs of their patients, including Plaintiff. Defendants, and each of them, also retained incompetent and dangerous service personnel, many of whom were not properly trained or qualified to care for patients, and/or who had dangerous propensities.
- 195. At all times relevant hereto, Defendant ORANGE TWIST knew of the need to comply with the laws applicable to the ownership, operation, management, and/or supervision of medical facilities, and further knew that non-compliance with such laws would put the health and welfare of personas such as Plaintiff at an unreasonable risk. The continual failure or refusal of Defendant to discharge its duties owed resulted in serious injury to Plaintiff.
- 196. Upon information and belief, at all times relevant hereto, Defendants, and each of them, had advance knowledge that their staff/employees/agents/contractors were unfit for the purposes of their employment yet employed said staff/employees/agents/contractors with a conscious disregard of the rights or safety of others, including Plaintiff.
- 197. Defendants, and each of them, failed to properly hire, train, and/or supervise their staff/employees/agents/contractors due to corporate negligence wherein each employed a system for hiring, training, and/or supervising that was established to maximize profits and gains with a conscious disregard for care and wellbeing of its patients, including Plaintiff, which caused or

contributed to unnecessary adverse outcomes for patients, including Plaintiff.

- 198. The conduct of Defendants, and each of them, was willful, intentional, oppressive, malicious, and done in a wanton and reckless disregard of Plaintiff's rights and thereby warrant the imposition of punitive damages.
- 199. Further, at all times relevant hereto, an officer, director or managing agent of Defendants, and each of them, who was expressly authorized to direct or ratify each employee/contractor/agent's conduct on behalf of said Defendants, have both expressly implied and ratified the wrongful conduct of its employees/contractors/agents as alleged herein by failing to discipline, investigate, terminate, and report said wrongful conduct, and by profiting from the conduct as alleged herein. As such, Defendants, and each of them, are liable to Plaintiff for punitive damages.
- 200. Defendants willfully and knowingly concealed information and the risk of PAH to Plaintiff, and were trained and instructed to materially omit such risks to the public including Plaintiff.
- 201. As a result of Defendants' breach, Plaintiff suffered the injuries and damages as alleged herein in an amount in excess of \$15,000.00.
- 202. As a further direct and proximate result, Plaintiff incurred expenses for medical care and treatment and will incur expenses for medical care and treatment in the future in an amount in excess of \$15,000.00. to be proven at trial.
- 203. As the actual, direct, proximate, and legal result of the acts and omissions of Defendants, Plaintiff has suffered and will continue to suffer significant physical injury, pain, suffering, permanent disfigurement, and extreme and severe mental anguish and emotional distress all to Plaintiff's damage in an amount in excess of \$15,000.00.
- 204. As a further proximate result of Defendants' negligence, Plaintiff suffered damages, including, but not limited to, pain and suffering.
- 205. As a further proximate result of Defendants' negligence, Plaintiff suffered permanent injury.
  - 206. As a direct and proximate result of Defendants' negligence, Plaintiff has had to

retain the services of THE VIEIRA FIRM to pursue this action and is entitled to recover costs of suit and reasonable attorney's fees incurred therein.

#### THIRD CAUSE OF ACTION

#### **Strict Products Liability**

(Against Defendant ZELTIQ)

- 207. Plaintiff repeats and realleges the allegations contained in the preceding paragraphs and the Declaration of Dr. Engineer attached hereto as *Exhibit 1*, as though fully set forth herein.
- 208. ZELTIQ designed, researched, developed, manufactured, tested, advertised, promoted, marketed sold, and/or distributed the CoolSculpting system and hardware. The CoolSculpting system and hardware, as designed, researched, developed, manufactured, tested, advertised, promoted, marketed, sold, maintained, and/or distributed by ZELTIQ, was an unsafe, defective, and unreasonably dangerous condition which was hazardous to patients. The substance was in this unsafe condition at the time it left the control and maintenance of ZELTIQ's possession.
- 209. The CoolSculpting system and hardware was expected to, and did, reach the usual consumers, handlers, and persons coming into contact with CoolSculpting system and hardware without substantial change in the condition in which it was designed, produced, manufactured, sold, distributed, and marketed by ZELTIQ.
- 210. Plaintiff was injured during the foreseeable use of the CoolSculpting system and hardware in a manner foreseeable to ZELTIQ.
  - 211. Upon information and belief, the CoolSculpting system and hardware failed to perform as safely as Plaintiff's medical providers expected, and/or represented to Plaintiff,
- 212. ZELTIQ's failure to design, manufacture, market, maintain and sell safe CoolSculpting systems was a proximate cause of Plaintiff's injuries and damages.
- 213. Additionally, as a direct and proximate result of ZELTIQ's placement of the defective CoolSculpting system and hardware into the stream of commerce, Plaintiff suffered permanent, catastrophic bodily injuries resulting in pain and suffering, disability, disfigurement, mental anguish, and loss of capacity for the enjoyment of life. The losses are either permanent or

continuing and Plaintiff will suffer the losses in the future.

- 214. ZELTIQ knew that CoolSculpting system was defective and unsafe, especially when used in the form and manner ZELTIQ intended and demonstrated.
- 215. ZELTIQ had a duty to design, manufacture, market, and sell a product that was not unreasonably dangerous for its normal, intended use.
- 216. ZELTIQ knew or should have known that CoolSculpting system was defective and unsafe, and with this knowledge, ZELTIQ voluntarily designed, manufactured, marketed, and sold their products in a defective condition for use by the public. Because ZELTIQ designed, researched, developed, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product, which when used in its intended or reasonably foreseeable manner, created an unreasonable risk to consumers and to Plaintiff, ZELTIQ is strictly liable for the injuries Plaintiff sustained.
- 217. As a direct and proximate result of the breach of duties by ZELTIQ, Plaintiff suffered injuries and damages as alleged herein in an amount in excess of \$15,000.00.
- 218. As the actual, direct, proximate, and legal result of the acts and omissions of Defendant, Plaintiff has suffered and will continue to suffer significant physical injury, pain, suffering, permanent disfigurement, and extreme and severe mental anguish and emotional distress all to Plaintiff's damage in an amount in excess of \$15,000.00.
- 219. As a further direct and proximate result, Plaintiff incurred expenses for medical care and treatment and will incur expenses for medical care and treatment in the future in an amount to be proven at trial.
- 220. Plaintiff has had to retain the services of THE VIEIRA FIRM to pursue this action and is entitled to recover costs of suit and reasonable attorney's fees incurred therein.

#### FOURTH CAUSE OF ACTION

# Violation Of Nevada Deceptive Trade Practices Act – NRS §§ 598.0903 to 598.0999 (Against All Defendants)

- 221. Plaintiff repeats and realleges the allegations contained in the preceding paragraphs and the Declaration of Dr. Engineer attached hereto as *Exhibit 1*, as though fully set forth herein.
  - 222. At all times relevant herein, Defendants violated the Nevada Deceptive Trade

Practices Act, §§ 598.0903 to 598.0999, by representing to its Nevada customers and consumers that their manufactured and sold products were safe and failed to take into consideration the damages consumers throughout Nevada would sustain through the use of Defendants' unsafe products.

- 223. Defendants made false or misleading statements of fact concerning the safety of their products and intentionally omitted reference to the dangerous and permanent conditions caused by CoolSculpting including but not limited to PAH, and otherwise made knowingly false representations in their communications with Nevada consumers by representing that their products were safe.
- 224. As a direct result of Defendants' conduct, Plaintiff has been deprived of fair and adequate CoolSculpting fat reduction treatment for which she paid, and to which she was fairly and lawfully entitled, and is now permanently disfigured and has to undergo invasive medical treatment as described herein.
- 225. The conduct of Defendants, and each of them, was willful, intentional, oppressive, malicious, and done in a wanton and reckless disregard Plaintiff's rights and thereby warrants the imposition of punitive damages.
- 226. Further, at all times relevant hereto, an officer, director or managing agent of Defendants, and each of them, who was expressly authorized to direct or ratify each employee/contractor/agent's conduct on behalf of said Defendants, have both expressly implied and ratified the wrongful conduct of its employees/contractors/agents as alleged herein by failing to discipline, investigate, terminate, and report said wrongful conduct, and by continuing to profit financially from said conduct. As such, Defendants, and each of them, are liable to Plaintiff for punitive damages.
- 227. As the actual, direct, proximate, and legal result of the acts of Defendants, and each of them, as alleged herein Plaintiff has suffered permanent and severe medical injuries, severe pain and suffering, loss of normal life, and disfigurement, and all to Plaintiff's damage in a sum in excess of \$15,000.00.
  - 228. As the actual, direct, proximate, and legal result of the acts of Defendants, and

each of them, as alleged herein Plaintiff has and will incur past, present, and future medical expenses as alleged herein, and all to Plaintiff's damage in a sum in excess of \$15,000.00.

- 229. As the actual, direct, proximate, and legal result of the acts and omissions of Defendants, Plaintiff has suffered and will continue to suffer significant physical injury, pain, suffering, permanent disfigurement, and extreme and severe mental anguish and emotional distress all to Plaintiff's damage in an amount in excess of \$15,000.00.
- 230. As a further direct and proximate result, Plaintiff incurred expenses for medical care and treatment and will incur expenses for medical care and treatment in the future in an amount to be proven at trial.
- 231. Plaintiff has had to retain the services of THE VIEIRA FIRM to pursue this action and is entitled to recover costs of suit and reasonable attorney's fees incurred therein.

#### FIFTH CAUSE OF ACTION

## Fraudulent Misrepresentation

(Against all Defendants)

- 232. Plaintiff repeats and realleges the allegations contained in the preceding paragraphs and the Declaration of Dr. Engineer attached hereto as *Exhibit 1*, as though fully set forth herein.
- 233. Defendants, and each of them, made a false representation to Plaintiff that the CoolSculpting treatment was safe.
- 234. Defendants, and each of them, omitted information regarding the risk of PAH, the injuries and damages caused by PAH, the need for multiple invasive surgical procedures to attempt to correct the damage caused by PAH, and the permanent disfigurement caused by PAH, thereby misrepresenting the risk of PAH.
- 235. Defendants, and each of them, knew or should have known that their representations made and those made by any employee/contractor/agent of Defendants, was false or that Defendants had an insufficient basis of information for making such misrepresentations and omissions.
- 236. Defendants, and each of them, intended to induce Plaintiff to receive CoolSculpting treatment because of the financial profit to be gained by Defendants from the procedure.

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- Plaintiff detrimentally relied on Defendants' misrepresentations, and paid 237. significant sums of money to obtain CoolSculpting treatment.
- The conduct of Defendants, and each of them, was willful, intentional, oppressive, malicious, and done in a wanton and reckless disregard Plaintiff's rights and thereby warrants the imposition of punitive damages.
- 239. Further, at all times relevant hereto, an officer, director or managing agent of Defendants, and each of them, who was expressly authorized to direct or ratify each employee/contractor/agent's conduct on behalf of said Defendants, have both expressly implied and ratified the wrongful conduct of its employees/contractors/agents as alleged herein by failing to discipline, investigate, terminate, and report said wrongful conduct, and by continuing to profit financially from said conduct. As such, Defendants, and each of them, are liable to Plaintiff for punitive damages.
- 240. As the actual, direct, proximate, and legal result of the acts and omissions of Defendants, Plaintiff has suffered and will continue to suffer significant physical injury, pain, suffering, permanent disfigurement, and extreme and severe mental anguish and emotional distress all to Plaintiff's damage in an amount in excess of \$15,000.00.
- 241. As a direct and proximate result of Defendants' misrepresentation and inducement, Plaintiff has been damaged in an amount in excess of \$15,000.00, including, but not limited to, bodily injury, and severe pain and suffering.
- 242. As a direct and proximate result of the acts of Defendants, Plaintiff has had to retain the services of THE VIEIRA FIRM to pursue this action and is entitled to recover costs of suit and reasonable attorneys' fees incurred therein.

### SIXTH CAUSE OF ACTION

## Fraudulent Concealment

(Against all Defendants)

- 243. Plaintiff repeats and realleges the allegations contained in the preceding paragraphs and the Declaration of Dr. Engineer attached hereto as *Exhibit 1*, as though fully set forth herein.
- 244. Defendants concealed or suppressed a material fact when they failed to apprise Plaintiff of the true nature of the CoolSculpting treatment and significant and appreciable risk of

PAH.

- 245. Defendants had a duty to disclose the true nature of the CoolSculpting treatment and significant and appreciable risk of PAH prior to any treatment being provided.
- 246. Defendants intentionally concealed or suppressed the fact regarding the nature of the CoolSculpting treatment and significant and appreciable risk of PAH, and administered CoolSculpting treatment to Plaintiff with the intent to defraud Plaintiff, and/or suppressed pertinent facts for the purpose of inducing Plaintiff to continue to use their services and remain under their care, for Defendants' financial gain.
- 247. Such concealment or suppression of facts induced Plaintiff to proceed with the CoolSculpting treatment because Plaintiff would have declined the treatment had she been fully apprised of the true nature of the CoolSculpting treatment and significant and appreciable risk of PAH.
- 248. Plaintiff was unaware of the true nature of the CoolSculpting treatment and significant and appreciable risk of PAH and would have declined to proceed with the treatment if she had known of the concealed or suppressed fact.
- 249. Defendant ORANGE TWIST continued its concealment and suppression of facts when it refused to provide Plaintiff with the medical records pertaining treatment rendered to Plaintiff at its facility.
- 250. At all times relevant hereto, Defendants, and each of them, placed Plaintiff in a "classic catch-22" by refusing to provide Plaintiff with the requested records and information, and instead requiring Plaintiff to file a complaint to enable Plaintiff to conduct discovery to ascertain the relevant information, making Plaintiff unable to file a complaint that contains the requisite particularity because Plaintiff does not know the information in Defendants' possession.<sup>14</sup>
- 251. Defendants, and each of them, breach of duties regarding record keeping encouraged and/or allowed its employees/agents/contractors to conceal the aforementioned facts

<sup>&</sup>lt;sup>14</sup> Rocker v. KPMG LLP, 122 Nev. 1185, 1193, 148 P.3d 703, 708 (2006), abrogated on other grounds by Buzz Stew, LLC v. City of N. Las Vegas, 124 Nev. 224, 181 P.3d 670 (2008).

and information from Plaintiff.

- 252. As a result of the concealment or suppression of the fact, Plaintiff sustained damages in an amount in excess of \$15,000.00, including, but not limited to, bodily injury, and severe pain and suffering.
- 253. The conduct of Defendants, and each of them, was willful, intentional, oppressive, malicious, and done in a wanton and reckless disregard Plaintiff's rights and thereby warrants the imposition of punitive damages in excess of \$15,000.00.
- 254. Further, at all times relevant hereto, an officer, director or managing agent of Defendants, and each of them, who was expressly authorized to direct or ratify each employee/contractor/agent's conduct on behalf of said Defendants, have both expressly implied and ratified the wrongful conduct of its employees/contractors/agents as alleged herein by failing to discipline, investigate, terminate, and report said wrongful conduct, and by continuing to profit financially from said conduct. As such, Defendants, and each of them, are liable to Plaintiff for punitive damages.
- 255. As the actual, direct, proximate, and legal result of the acts and omissions of Defendants, Plaintiff has suffered and will continue to suffer significant physical injury, pain, suffering, permanent disfigurement, and extreme and severe mental anguish and emotional distress all to Plaintiff's damage in an amount in excess of \$15,000.00.
- 256. As a direct and proximate result of the acts of Defendants, Plaintiff has had to retain the services of THE VIEIRA FIRM to pursue this action and is entitled to recover costs of suit and reasonable attorneys' fees incurred therein.

#### **SEVENTH CAUSE OF ACTION**

## Negligent Failure to Retain Records Pursuant to NRS 629.051 (Against Orange Twist, LLC)

- 257. Plaintiff repeats and realleges the allegations contained in the preceding paragraphs and the Declaration of Dr. Engineer attached hereto as *Exhibit 1*, as though fully set forth herein.
- 258. Plaintiff requested a full and complete set of her medical and billing records and ORANGE TWIST failed to provide Plaintiff her medical and billing records.
  - 259. ORANGE TWIST had a duty to maintain and keep full, complete, and accurate

records relating to the medical history, examination, diagnosis and/or treatment of patients, including Plaintiff, and to provide a full and complete copy of said records upon request pursuant to NRS Chapter 629.

- 260. Upon information and belief, ORANGE TWIST breached its duties when it failed to implement a reasonable record-keeping system, failed to require that its employees/agents/contractors/staff appropriately document the assessment, triage, care, treatment and/or condition of patients, resulting in a failure to properly track or document the assessment, triage, care, treatment, condition, and needs of patients presenting to ORANGE TWIST for treatment, including Plaintiff.
- 261. ORANGE TWIST failed to properly implement a reasonable record-keeping system due to corporate negligence wherein each chose to employ a record-keeping system that was established to maximize profits and gains with a conscious disregard for the care and wellbeing of its patients, resulting in a general failure to document the assessment, triage, care, treatment, conditions and/or needs of its patients, contributing to and causing unnecessary adverse outcomes for patients, including for Plaintiff.
- 262. As the actual, direct, proximate, and legal result of the acts and omissions of Defendants, Plaintiff has suffered and will continue to suffer significant physical injury, pain, suffering, permanent disfigurement, and extreme and severe mental anguish and emotional distress all to Plaintiff's damage in an amount in excess of \$15,000.00.
- 263. As a direct and proximate result of the acts of ORANGE TWIST, Plaintiff has had to retain the services of THE VIEIRA FIRM to pursue this action and is entitled to recover costs of suit and reasonable attorneys' fees incurred therein.

WHEREFORE, Plaintiff expressly reserving the right to amend this complaint prior to or at the time of trial of this action, to insert those items of damage not yet fully ascertainable, prays for judgment against the Defendants, and each of them, as follows:

- 1. For general damages in an amount in excess \$15,000.00;
- 2. For special damages in an amount in excess of \$15,000,00;
- 3. For general damages for pain, suffering, mental distress, disfigurement, anguish

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and fear, to be determined at trial;

- 4. For punitive damages under NRS Chapter 42;
- 5. For any and all pre- and post-judgment interest allowed under the law;
- 6. For reasonable attorney's fees plus costs of suit, and
- 7. For such other and further relief as the court may deem just and proper.
- 8. DATED this 23rd day of May, 2022.

#### THE VIEIRA FIRM

By: _	/s/ Andréa L. Vieira
•	ANDRÉA L. VIEIRA, ESQ.
	Nevada Bar No. 15667
	THE VIEIRA FIRM
	3100 W. Charleston Blvd., Ste. 200
	Las Vegas, Nevada 89102
	Telephone: (702) 793-3160
	Facsimile: (702) 637-4722
	Attorney for Plaintiff

# EXHIBIT 1

#### DECLARATION OF NITIN ENGINEER, M.D. PURSUANT TO NRS 41A.071

I, Nitin J. Engineer, M.D., F.A.C.S., hereby declare:

- 1. I am a physician licensed to practice medicine in Nevada and the founder, CEO, and principal surgeon at Engineered Aesthetics Plastic Surgery Institute.
- 2. I completed my undergraduate degree at Vanderbilt University in 1996 and completed my Doctorate of Medicine at Vanderbilt University School of Medicine in 2000.
- 3. I completed my General Surgery internship at the University of Washington School of Medicine and my General Surgery residency at Southern Illinois University School of Medicine.
- 4. I completed a fellowship in Hand and Microvascular Surgery with the Division of Plastic Surgery at Southern Illinois University School of Medicine.
- 5. I have served as Clinical Instructor with the Department of Surgery at the University of Louisville School of Medicine.
- 6. I have also completed training in Plastic and Reconstructive Surgery at the University of Louisville School of Medicine, receiving the Clinical Excellence Award in 2019.
- 7. I am a Fellow of the American College of Surgeons (FACS) and have achieved board certification in General Surgery and Hand and Microvascular Surgery and am board-eligible in Plastic and Reconstructive Surgery.
- 8. I am a member of the American College of Surgeons (ACS), the American Society for Surgery of the Hand (ASSH), the American Association for Hand Surgery (AAHS), the American Society for Peripheral Nerve (ASPN), and the American Association for Reconstructive Microsurgery (ASRM).
- 9. I am also a candidate member of the American Society of Plastic Surgeons (ASPS) and the American Society for Aesthetic Plastics Surgeons (ASAPS).
- 10. I have extensive experience in an array of nonsurgical aesthetic treatment options including injections with neuromodulators (e.g. Botox, Dysport, Jeuveau) and hyaluronic acid fillers (e.g. Juvederm and Restylane), Sculptra, chemical peels, laser therapy, and numerous other skin rejuvenation products.

- 11. I am also knowledgeable of the standards of care and proper FDA procedures for approved substances.
- 12. I have been requested to opine about the treatment and evaluation of Michele Brown's medical condition in relation to the Cryolipolysis (CoolSculpting®) treatment she received at Illuminate, now known as Orange Twist.
  - 13. All opinions are stated herein to a reasonable degree of medical probability.
- 14. On or about in July 2019, Michele Brown underwent a Cryolipolysis (CoolSculpting®) treatment in the neck area at Illuminate, now known as Orange Twist.
  - 15. Ms. Brown noticed enlargement in the area several months after the procedure.
- 16. On or about February 5, 2020, Ms. Brown presented to Cameron Earl, M.D. at Earl Plastic Surgery, who noted that Ms. Brown had undergone a CoolSculpting treatment on her chin. Following that treatment, her chin and neck area had paradoxically increased in size. In addition, she had also undergone a Kybella treatment, after which there was also an increase in size. Therefore, Ms. Brown was requesting a surgical consultation.
- 17. Dr. Earl noted Ms. Brown's (Head, Ears, Eyes, Nose, and Throat) HEENT physical examination was significant for a submental fat prominence. However, he recommended against any surgical intervention and recommended that Ms. Brown lose weight at the rate of 1 pound per month and return in one year.
- 18. Dr. Earl also noted that Ms. Brown had a previous diagnosis of left breast cancer in 2010, for which she underwent a left mastectomy and reconstruction.
- 19. On September 29, 2020, Ms. Brown presented to Dr. Lanfranchi at The Lanfranchi Center for a free consultation. Dr. Lanfranchi took photos of Ms. Brown's face and head area but did not prepare a consultation report.
- 20. On November 3, 2020, Ms. Brown presented to Randall Weingarten, M.D. who noted a submental collection of fat and whose impression was that Ms. Brown had a lipoma.
- 21. A lipoma is fatty tumor located in the subcutaneous space. It is usually a slow-growing, fatty lump that is most often situated between the skin and the underlying muscle layer.
  - 22. Dr. Weingarten recommended that Ms. Brown consult with a plastic surgeon.

- 23. On November 18, 2020, Ms. Brown underwent a CT scan of the neck with contrast at Desert Radiology, which revealed a "Slight asymmetric inferoanterior extension of the left submandibular gland compared to that of the right. Otherwise, no definite CT abnormality to correspond with reported palpable anterior neck lump."
- 24. On December 16, 2020, Ms. Brown presented to Anson and Higgins plastic surgery for a consultation. She was referred to an Ear, Nose, and Throat, ("ENT") specialist and a recommendation for another opinion.
- 25. On January 15, 2021, Ms. Brown presented to Jo-Lawrence Bigcas, M.D. in the Department of Otolaryngology Head & Neck Surgery Department at UNLV who diagnosed Ms. Brown with a submental fat deposit and referred her to the Division of Plastics & Reconstructive Surgery at UNLV for an opinion regarding liposuction and fat removal for the chin and neck area.
- 26. On March 9, 2021, Ms. Brown presented to Joshua Goldman, M.D. at UNLV Medicine Department of Plastic & Reconstructive Surgery. During this visit Dr. Goldman mentioned to Ms. Brown that he had previously read about and had a patient during his subspecialty training with Paradoxcial Adipose Hyperplasia ("PAH") as a result of cryolypolysis and that PAH was potentially the cause of Ms. Brown's increased fat in such an isolated area.
  - 27. This was the first time that PAH was mentioned to Ms. Brown.
  - 28. PAH is solely attributed to the Cryolipolysis (CoolSculpting®) procedure.
- 29. Dr. Goldman recommended submental incision with direct excision combined with liposuction and possible platysmaplasty.
- 30. On May 5, 2021, Ms. Brown underwent a Liposuction and Platysmaplasty procedure with Dr. Goldman at Sahara Surgery Center. Dr. Goldman noted that the cryolipolysis performed to her submental area caused hyperplasia of the fat cells in the area resulting in a contour deformity.
- 31. Dr. Goldman pre-tunneled with a 3mm cannula, performed liposuction, during which 50 cc of lipoaspirate was obtained, and made a 4 cm incision to directly excise some fat centrally and laterally. Dr. Goldman then performed a platysmaplasty by plicating the two medial layers of the platysma with a 2-0 PDS suture.

- 32. On May 11, 2021, Ms. Brown returned to Dr. Goldman for a follow up and suture removal. Dr. Goldman recommended that Ms. Brown wear a jaw bra at night.
- 33. On June 22, 2021, Ms. Brown presented to Dr. Goldman who noted mild ecchymosis resolved with improved swelling but not complete resolution.
- 34. On August 24, 2021, Ms. Brown returned to Dr. Goldman who discussed more smoothing of her residual contour irregularity with fillers versus Kybella, and discussed the aesthetics of her jowls.
- 35. On November 9, 2021, it was recommended that Ms. Brown undergo additional surgical procedures including a second liposuction procedure and a full face and neck lift.
- 36. The Cryolipolysis (CoolSculpting®) treatment that Ms. Brown received at Illuminate, now known as Orange Twist, fell below the standard of care and caused the PAH she experienced.
- 37. Ms. Brown was not provided with accurate and adequate informed consent prior to and regarding the Cryolipolysis (CoolSculpting®) treatment and was not provided with accurate and adequate information regarding reasonable risks, possible side effects, benefits and purposes of the procedure including, but not limited to, PAH.
- 38. Based on data from the manufacturer of the Cryolipolysis (CoolSculpting®) equipment, PAH has been estimated to occur in 1 out of every 4,000 treatment cycles, for an incidence of 0.025%, but a study led by ASPS Member Surgeons Michael E. Kelly, MD, and Jose Rodríguez-Feliz, MD, of Miami Plastic Surgery noted that their experience of 15 PAH events in 6 patients represents a much higher incidence: 0.72%, or about 1 out of every 138 cryolipolysis treatments.
  - 39. It is common that more than one liposuction treatment is needed to treat PAH cases.
- 40. Because the Cryolipolysis (CoolSculpting®) procedure is marketed as a non-invasive treatment, it is upsetting to patients to have to undergo multiple invasive surgical procedures to correct the effects of PAH. Failure of Illuminate, now known as Orange Twist, to inform Ms. Brown of this possibility fell below the standard of care.

- 41. Failure of Illuminate, now known as Orange Twist, to inform Ms. Brown that she could be left permanently disfigured fell below the standard of care.
- 42. Based on the foregoing, it is my opinion, to a reasonable degree of medical probability that the Cryolipolysis (CoolSculpting®) procedure performed on Ms. Brown is the direct cause of her PAH diagnosis received on March 9, 2021, and that Illuminate, now known as Orange Twist, failed to meet the standard of care and treatment for Ms. Brown by failing to accurately and adequately inform Ms. Brown regarding the procedure and its reasonable risks and possible side effects, specifically PAH.
- 43. Illuminate, now known as Orange Twist, had a duty to properly, hire, train, and supervise its employees, contractors, and agents to ensure that patients, such as Ms. Brown, were provided with proper treatment and were accurately and adequately informed of the reasonable risks and possible side effects of the procedures they were undergoing. It is my opinion that Illuminate, now known as Orange Twist, failed in that duty.

I declare under penalty of perjury under the laws of the State of Nevada that the foregoing is true and correct.

DATED this 22 day of February, 2022.

Nitin J. Engineer, MD, FACS

Plastic Surgeon • Aesthetic | Reconstructive | Hand Engineered Aesthetics Plastic Surgery Institute

Page 5 of 5

## NITIN JAGDISH ENGINEER, MD, FACS CURRICULUM VITAE

Employment and Academic Appointments	
01/20-Present: Engineered Aesthetics <sup>TM</sup> Plastic Surgery Institute —Founder, CEO, and Medical Director; Plastic Surgeon	Henderson, Nevada
10/2013-12/2019: EXTREMICURE® Hand Center —Founder, CEO, and Medical Director; Hand and Microvas	Henderson, Nevada cular Surgeon
04/2012-Present: Touro Univ. Nevada College of Osteopathic Medicine —Adjunct Instructor, Hand and Microsurgery	Las Vegas, Nevada
05/2011-10/2013: St. Michael's Center for Special Surgery —Medical Director	Henderson, Nevada
05/2009-10/2013: Brown Hand Center —Attending Physician, Hand and Microsurgery	Henderson, Nevada
07/2008-05/2009: Inspire Medical —Independent Contract Emergency Room Physician	Louisville, Kentucky
10/2007-09/2008: University of Louisville School of Medicine —Clinical Instructor, Hand and Microsurgery, Department of	Louisville, Kentucky f Surgery
Education 11/2016-10/2019: University of Louisville School of Medicine —Plastic and Reconstructive Surgery Fellow, Division of Plast	Louisville, Kentucky tic Surgery
09/2006-08/2007: Southern Illinois University School of Medicine —Hand and Microsurgery Fellow, Division of Plastic Surgery	Springfield, Illinois
07/2002-06/2006: Southern Illinois University School of Medicine —Resident (PGY-3, PGY-4, PGY-5), Department of General Su	Springfield, Illinois rgery
06/2000-06/2002: University of Washington School of Medicine —Resident (PGY-1, PGY-2), Department of General Surgery	Seattle, Washington
08/1996-05/2000: Vanderbilt University School of Medicine —Doctor of Medicine, May 2000	Nashville, Tennessee
08/1992-05/1996: Vanderbilt University —Bachelor of Arts, French (cum laude), May 1996	Nashville, Tennessee
<u>Certification</u> Board Certified Diplomate of the American Board of Surgery – Surgery #53760 November 4, 2019	: Recertification -
Board Certified Diplomate of the American Board of Surgery – Hand Surgery #	305: September 10, 2012
Fellow of the American College of Surgeons (FACS): October 11, 2009	
Board Certified Diplomate of the American Board of Surgery – Surgery #53760	: October 27, 2008
American Board of Surgery Certifying Oral Examination: Passed October 27, 20	008
American Board of Surgery Qualifying Written Examination: Passed August 10	, 2006
United States Medical Licensing Examination (USMLE Step I, II, III) Complete	d 2006

Basic Life Support Provider: July 10, 2009 (Renewed February 6, 2020)

Advanced Cardiovascular Life Support Provider: November 8, 2007 (Renewed February 6, 2020)

Pediatric Advanced Life Support Program: July 1, 2008 (Renewed 2016)

#### **Continuing Education**

Dallas Cosmetic<sup>TM</sup> - Surgery and Medicine Meeting - Patient Safety and Advances - March 20-21, 2019

Dallas Rhinoplasty<sup>TM</sup> Meetin – Finesse and Refinements – March 22-23, 2019

St. Louis University School of Medicine Practical Anatomy & Surgical Education – Advanced Techniques for Facial Rejuvenation - November 4, 2019

Salzman Cosmetic Surgery and Spa Course on Ultrasound For Plastic Surgeons - December 16, 2018

#### **Medical Licensure**

Nevada Medical License: Active/Unlimited #13102 (Date of Expiration: June 30, 2021)

Arizona Medical License: Active/Unlimited # 40241 (Date of Expiration: August 24, 2020)

Kentucky Medical License: Active/Unlimited # 41501 (Date of Expiration: February 29, 2020)

#### Honors and Awards

2019: **THIRD PLACE** – Kentucky Society of Plastic Surgeons Resident Research Competition.

A Single Center Review of Early Experience with Poly-4-Hydroxybutyrate (P4HB) Surgical Scaffold in the Treatment of Breast Implant Malposition.

2019: Clinical Excellence Award, University of Louisville Division of Plastic Surgery

2018: On-Time Doctor Award, Vitals.com

2014, 2016, 2017, 2018: Compassionate Doctor Recognition, Vitals.com

2014, 2016, 2017, 2018: Patients' Choice Award, Vitals.com

2014: Top Doctor of Southern Nevada Award - Vegas Inc. HealthCare Quarterly Magazine

2005: Excellence in Teaching Award, Southern Illinois University Department of Surgery

2004: Excellence in Teaching Award, Southern Illinois University Department of Surgery

2003: Excellence in Teaching Award, Southern Illinois University Department of Surgery

#### Research Experience and Presentations

2019: Engineer NJ, Moore E, Mays C, Calobrace MB. A Single Center Review of Early Experience with Poly-4-Hydroxybutyrate (P4HB) Surgical Scaffold in the Treatment of Breast Implant Malposition. (Presented at Kentucky Society of Plastic Surgeons - October 11, 2019). Division of Plastic Surgery, University of Louisville School of Medicine. CaloAesthetics Plastic Surgery Center.

2019: Thatikunta M, Bumpous J, Little JA, Karia S, Herring NR, Nuru M, Engineer NJ, Mutchnick, I. Repair of a large primary subtemporal encephalocele in a 3-year-old child: case report. Journal of Neurosurgery. 2018 October.
Department of Neurosurgery, University of Louisville School of Medicine.

2018: Engineer NJ, Kachare SD, Little JA. Immediate Earlobe Reconstruction: Skin flap modifications to

- Improve sensation and aesthetic appearance. (Presented at Kentucky Society of Plastic Surgeons October 11, 2019).
- Division of Plastic Surgery, University of Louisville School of Medicine.
- 2012: Hazani R, <u>Engineer NJ</u>, Elston J, Wilhelmi BJ. Anatomic Landmarks for Basal Joint Injections. Journal of Burns and Wounds [available at <u>www.eplasty.com</u>]. 2012 January; 12:14-18. Department of Surgery, University of Louisville School of Medicine.
- 2008: Engineer NJ, Hazani R, Wilhelmi BJ. Variations in the anatomy of the third common digital nerve and landmarks to avoid injury to the third common digital nerve with carpal tunnel release. Journal Burns and Wounds [available at <a href="www.eplasty.com">www.eplasty.com</a>]. 2008 October; 8. Department of Surgery, University of Louisville School of Medicine.
- 2008: Hazani R, <u>Engineer NJ</u>, Zeineh LL, Wilhelmi BJ. Assessment of the distal extent of the A1 pulley release: a new technique. Journal of Burns and Wounds [available at <u>www.eplasty.com</u>]. 2008 August; 8: 1-4.

  Department of Surgery, University of Louisville School of Medicine.
- 2008: Hazani R, <u>Engineer NJ</u>, Wilhemi BJ. Anatomic landmarks of the radial tunnel. Journal of Burns and Wounds [available at <u>www.eplasty.com</u>]. 2008 June; 8: 377-82. Department of Surgery, University of Louisville School of Medicine.
- 2007: Hazani R, <u>Engineer NJ</u>. Surreptitious injection of mineral oil: a case report of sclerosing lipogranulomatosis. Annals of Plast Surg. 2008 Nov; 61(5):555-8. Division of Plastic Surgery, Loma Linda University School of Medicine.
- 2007: Engineer NJ, Neumeister MW. Endoscopic carpal tunnel release: an anatomic study of complications and revisions of trocar placement. (Poster presentation at SIU Research Day) Division of Plastic Surgery, Southern Illinois University School of Medicine.
- 2007: Russell RC, Neumeister MW, Ostric SA, <u>Engineer NJ</u>. Extremity reconstruction using nonreplantable tissue ("spare parts"). <u>Clin Plast Surg.</u> 2007 Apr; 34(2):211-22. Division of Plastic Surgery, Southern Illinois University School of Medicine.
- 2006: Cooney DS, <u>Engineer NJ</u>, Wilhelmi BJ. Removal of a portion of the dorsal lip of the radius during proximal row carpectomy. <u>Hand.</u> 2006 June; 1(1):20. Division of Plastic Surgery, Southern Illinois University School of Medicine.
- 2006: Cooney DS, <u>Engineer NJ</u>, Wilhelmi BJ. Comparison of trapeziometacarpal joint reconstruction by alternate methods of tendon arthroplasty. <u>Hand.</u> 2006 June; 1(1):23. Division of Plastic Surgery, Southern Illinois University School of Medicine.
- 2005: Cooney DS, Neumeister MW, Wilhelmi BJ, <u>Engineer NJ</u>, Evans S. Comparison of trapeziometacarpal joint reconstruction by alternate methods of tendon arthroplasty. <u>PRS</u>. 2005 September; 116(3): 84-85.
   Division of Plastic Surgery, Southern Illinois University School of Medicine.
- 2005: Cooney DS, <u>Engineer NJ</u>, Evans S, Neumeister MW, Wilhelmi BJ. Comparison of trapeziometacarpal joint reconstruction by alternate methods of tendon arthroplasty. (Presented at American Society of Plastic Surgeons September 27, 2005)
  Division of Plastic Surgery, Southern Illinois University School of Medicine.

#### Lectures

- 2019: <u>Engineer NJ</u>. Facelift. (Grand Rounds Lecture)

  Division of Plastic Surgery, University of Louisville School of Medicine
- 2019: <u>Engineer NJ</u>. Extensor Tendons. (Hand Conference Lecture)
  Division of Plastic Surgery, University of Louisville School of Medicine
- 2019: Engineer NJ. Body Contouring for Weight Loss Patients. (Grand Rounds Lecture)

- Division of Plastic Surgery, University of Louisville School of Medicine
- 2019: <u>Engineer NJ</u>. Pelvic Reconstruction and Gender Related Surgeries. (Grand Rounds Lecture) Division of Plastic Surgery, University of Louisville School of Medicine
- 2019: Engineer NJ. Basilar Joint Arthritis. (Hand Conference Lecture) Division of Plastic Surgery, University of Louisville School of Medicine
- 2018: <u>Engineer NJ</u>. Hand Tumors. (Hand Conference Lecture)

  Division of Plastic Surgery, University of Louisville School of Medicine
- 2018: <u>Engineer NJ</u>. Mandible Fractures. (Grand Rounds Lecture)

  Division of Plastic Surgery, University of Louisville School of Medicine
- 2018: <u>Engineer NJ</u>. Hair Restoration. (Grand Rounds Lecture)
  Division of Plastic Surgery, University of Louisville School of Medicine
- 2018: <u>Engineer NJ</u>. Liposuction. (Grand Rounds Lecture)

  Division of Plastic Surgery, University of Louisville School of Medicine
- 2017: <u>Engineer NJ</u>. Joint Dislocations. (Hand Conference Lecture)

  Division of Plastic Surgery, University of Louisville School of Medicine
- 2017: <u>Engineer NJ</u>. Dupuytren's Contracture. (Hand Conference Lecture)
  Division of Plastic Surgery, University of Louisville School of Medicine
- 2017: <u>Engineer NJ</u>. Hand Infections. (Hand Conference Lecture)

  Division of Plastic Surgery, University of Louisville School of Medicine
- 2017: <u>Engineer NJ</u>. Tenosynovitis Conditions. (Hand Conference Lecture)
  Division of Plastic Surgery, University of Louisville School of Medicine
- 2013: <u>Engineer NJ</u>. Common problems of the hand and upper extremity. (Lecture)
  Evening with a Doc Barbara Greenspun Women's Care Center Lecture Series,
  St. Rose Dominican Hospital Siena Campus, Henderson, Nevada
- 2012: <u>Engineer NJ</u>. Pronator syndrome. (Lecture)

  Annual Symposium Lecture Series, Association of Extremity Nerve Surgeons, Scottsdale, Arizona.

#### **Memberships**

2013-Present: Active Member - American Society for Surgery of the Hand (ASSH)

2012-2014: Fellow - Association of Extremity Nerve Surgeons (AENS)

2010-Present: Active Patron Member - American Association of Physicians of Indian Origin (AAPI)

2003-Present: Active Member - American College of Surgeons (ACS)

2008-Present: Active Member - American Association for Hand Surgery (AAHS)

2008-Present: Active Member – American Association for Reconstructive Microsurgery (ASRM)

2008-Present: Active Member – American Association for Peripheral Nerve (ASPN)

2007-2008: Kentucky Medical Association (KMA)

2007-2008: Greater Louisville Medical Society (GLMS)

2002-2007: Illinois State Medical Society (ISMS)

1996-2008: American Medical Association (AMA)

#### **Employment and Volunteer Activities**

2011: People to People Citizen Ambassador Program, American College of Surgeons: Delhi, India Surgical Leadership and Service Delegation to promote cross-cultural exchange of information regarding the practice of medicine in the United States and India and provide volunteer medical care to underprivileged areas in rural India (Sohna Village)

1995-1996: Computer Systems Support Technician (Summer—Paris and Mulhouse, France)

1994-1998: ASB (Alternative Spring Break, Volunteer Organization): Kyle, South Dakota (1998); Detroit, Michigan (1997); Tahlequah, Oklahoma (1996); Charleston, South Carolina (1994)

1993-1996: Anesthesia Technician, Medical Center of Central Georgia (Macon, Georgia)

#### Foreign Languages

English (fluent), Hindi (proficient), French (proficient), and German (intermediate)



## MEDICAL FEE SCHEDULE

Service Description		Fee
Physician Record Review	This fee represents the amount of time the expert has spent reviewing medical records, x-rays and all diagnostic studies in the preparation of a report following an examination or after receiving additional medical records and issuing a supplemental report	\$225/15 mins or \$1,100/hour
Medical Evaluation	This fee is for the direct face-to-face interaction between the expert and the plaintiff being evaluated.	\$1,200
Extended Medical Evaluation	This fee is for the direct face-to-face interaction between the expert and the plaintiff being evaluated for complex cases requiring greater than 60 minutes.	\$1,500
Medical Evaluation w/Interpreter	These are the same services that are provided as listed above, however the evaluation normally takes much longer due to the necessity of an interpreter	\$1,500
Consultation Scheduling Retainer	This deposit ensures good faith that the patient will appear for their medical evaluation and is required to schedule the appointment.	\$400
Narrative Report	This fee represents the preparation of the report by the expert after obtaining the history, performing the examination, and reviewing the submitted medical records and diagnostic studies	\$900/hour
Supplemental Report	This fee represents the preparation of the supplemental report by the expert	
Literature Research	As is deemed necessary by the expert pursuant to questions posed by the requester, on occasion there is necessity for review of medical literature	\$900/hour
Deposition Review	This fee represents the time spent by the expert for the review of all depositions	
Deposition Prep Time & Pre-Deposition Conference  This is applicable in situations where there are extensive medical records, and a significant amount of time has passed since the evaluation		\$1,100/hour
In-Person Deposition Testimony / Video Deposition Testimony	This fee represents the time spent by the expert to provide expert testimony. There is a one-hour minimum payable in advance or the time the deposition commences.  All balances will be billed to the deposing attorney. The attorney who has engaged	
Trial / Arbitration Prep Time	This fee represents the time spent by the expert in reviewing the medical records prior to trial or arbitration testimony. On many occasions there has been a period	
Review of Video	This fee represents the time spent by the expert regarding reviewing video surveillance or accident scene investigation.	\$1,100/hour
Expedited Report Services	The normal turnaround from the time of the evaluation to submission of the report is 30 days. Preparation of expedited reports, either written or via telephone conference required in less than 30 days is subject to the fees listed in addition to the regular fees listed. The preparation of an expedited report demands that the	0-2 Days \$2,000 3-7 Days \$1,500 8-15 Days \$1,000
	expert set aside all other work and focus on the preparation of the expedited report.	15-30 Days \$800



Service	Description	Fee
Arbitration / Trial Testimony	L experience if requires the expert to schedule either a half-day or full day away from L	
Travel Expenses	Travel fees are for expenses and time for travel to evaluations, depositions, trial, arbitration, or conferences outside the expert's immediate area and can include driving time air travels costs, hotels, and parking etc.	\$500/hour plus expenses
Telephone Calls / Conferences	This fee represents the time spent by the expert telephone conferencing with the requestor.	\$900/hour
Staff Compilation of Records		\$200hour
Copy / Printing Fees	This fee represents the per page for copying existing records or printing records from CD or sent via email or double-sided records that need to be copied to single sided.	15 cents/page
	Cancellation Policies & Fees	
Failure to Appear Fee	This cancellation fee is applied if any party affiliated with the involved case fails to appear without notice at any scheduled consultation, conference, deposition, or testimony for which the expert is scheduled. This creates significant inconvenience for the expert who has set this time aside.	\$2,000
Late Cancellation Fee  This cancellation fee is applied if there is a cancellation with less than five days' notice for any consultation, conference, deposition, or testimony for which the expert is scheduled. This creates significant inconvenience for the expert who has set this time aside.		\$1,500
Arbitration / Trial	Once an expert has committed to being available for arbitration and/ or trial testimony, a half day or full day will be set aside. With less than four days' notice it	6 or more working days' notice—full refund
Testimony	is not possible for an expert to schedule surgical procedures or make themselves available for patient examinations.	5 or less working days' notice—No refund
Late Deposition Payment Fee  Payment should be received in the office 5 days prior to the deposition. If payment is not received by the date of the deposition, a 50% late fee will be charged.		50% of agreed expense fee



## **History of Testimony & Trial**

Date:	Patient/Physician:	Case Type:	Review Type:
11.21.2013	Michael Jones	Worker's Compensation	Deposition
02.24.2014	Tyson Cobb, MD	Medical Legal	Review of Records & Expert Opinion Letter
07.11.2014	Tamela T. Goodwin	Personal Injury	Deposition
03.07.2015	Amy Kraus	Personal Injury	Review of Records & Expert Opinion Letter
04.13.2015	Jaquin Fielder	Personal Injury	Deposition
08.31.2015	Afshin Tadayon	Personal Injury	Deposition
12.21.2015	Marisol Aguayo	Medical Legal	Review of Records & Expert Opinion Letter
01.29.2016	Sueae Yi	Personal Injury	Review of Records & Expert Opinion Letter
02.15.2016	Lilia Payne	Personal Injury	Review of Records & Expert Opinion Letter
02.15.2016	Sadie Gibbs	Medical Legal	Review of Records & Expert Opinion Letter
03.14.2016	Steven Thomas	Personal Injury	Deposition
03.14.2016	Maria Adamson	Personal Injury	Deposition
03.30.2016	Latisha Springs	Personal Injury	Review of Records & Expert Opinion Letter



07.22.2016	Maria Alviso	Personal Injury	Review of Records & Expert Opinion Letter
07.28.2016	Marisol Aguayo	Medical Legal	Deposition
08.10.2016	Gerald Pederson	Personal Injury	Review of Records & Expert Opinion Letter
08.22.2016	Littlefield, Wendy	Personal Injury	Review of Records & Expert Opinion Letter
08.24.2016	Dima Ali	Personal Injury	Review of Records & Expert Opinion Letter
08.23.2016	Anna Gallegos	Personal Injury	Review of Records & Expert Opinion Letter
10.26.2016	Becky Bradley	Personal Injury	Review of Records & Expert Opinion Letter
12.01.2016	Becky Bradley	Personal Injury	Review of Records & Expert Opinion Letter (Rebuttal)
12.30.2016	Angelica Sutton	Personal Injury	Deposition
03.01.2017	Becky Bradley	Personal Injury	Review of Records & Expert Opinion Letter (Rebuttal)
05.19.2017	Anna Gallegos	Personal Injury	Review of Records & Expert Opinion Letter (Rebuttal)
06.18.2017	Loretta Craig-Maul	Personal Injury	Review of Records & Expert Opinion Letter
09.21.2017	Christopher Edwards	Personal Injury	Review of Records & Expert Opinion Letter



11.07.2018	Christopher Edwards	Personal Injury	Deposition
05.12.2018	Beau Budde	Personal Injury	Deposition
03.11.2019	Philip Poli	Personal Injury	Deposition
09.17.2020	Taylor Ross	Personal Injury	Expert Witness In Trial
10.04.2020	Anthony Fitzgerald	Personal Injury	Review of Records & Expert Opinion Letter
11.16.2020	Colton Weaver	Personal Injury	Review of Records, IME Expert Opinion Letter (Rebuttal) & Life Care Plan
12.01.2020	Bau Lam	Personal Injury	IME & Expert Opinion Letter
01.14.2021	Raina Torres	Personal Injury	Review of Records, IME & Expert Opinion Letter
01.28.2021	Rosemary Stevens	Personal Injury	Review of Records & Expert Opinion Letter
02.01.2021	Lori Battaglia	Personal Injury	Review of Records, IME & Expert Opinion Letter
02.18.2021	Colton Weaver	Personal Injury	Deposition
04.01.2021	Amanda Asuega	Personal Injury	Review of Records, IME & Expert Opinion Letter
05.10.2021	Isabel Manguia	Personal Injury	Review of Records, IME & Expert Opinion Letter
05.10.2021	Mercedes Sanchez	Personal Injury	Review of Records & Expert Opinion Letter
06.01.2021	Tammy Crowdis	Personal Injury	Review of Records, IME & Expert Opinion Letter



07.13.2021	Tammy Crowdis	Personal Injury	Rebuttal Report
07.26.2021	Tammy Crowdis	Personal Injury	Deposition
09.01.2021	Alis Nordwig	Personal Injury	Review of Records, IME & Expert Opinion Letter
09.01.2021	Diane Shoessow	Personal Injury	Review of Records & Expert Opinion Letter
09.22.2021	Lloyd Benson	Personal Injury	IME & Expert Opinion Letter
10.14.2021	Amanda Asuega	Personal Injury	Deposition
10.14.2021	Amanda Asuega	Personal Injury	Rebuttal Report
10.19.2021	Heather Littlefield	Personal Injury	Expert Opinion Letter, IME & Life Care Plan
10.29.2021	Joseph Moore	Personal Injury	Review of Records, IME & Expert Opinion Letter
11.28.2021	Alis Nordwig	Personal Injury	Rebuttal Report
11.10.2021	Senarath Ekanayake	Personal Injury	Review of Records, IME & Expert Opinion Letter
11.29.2021	Lloyd Benson	Personal Injury	Deposition
11.30.2021	Joseph Triston	Personal Injury	Review of Records & Expert Opinion Letter

If you intend to defend this lawsuit, within 21 calendar days<sup>1</sup> after this Summons is served

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other form of relief.

<sup>&</sup>lt;sup>1</sup> The State of Nevada, its political subdivisions, agencies, officers, employees, board members, commission members, and legislators each have 45 days after service of this Summons within which to file a response to Plaintiff's complaint.

1 on you (not counting the day of service), you must: 2 File with the Clerk of the Court, whose address is shown below, a formal written 3 response (typically a legal document called an "answer," but potentially some other response) to Plaintiff's complaint. 4 5 2. Pay the required filing fee to the court, or file an Application to Proceed In Forma 6 Pauperis and request a waiver of the filing fee. 7 3. Serve (by mail or hand delivery) a copy of your response upon the Plaintiff whose 8 name and address is shown below. 9 Information and forms to assist you are available, free of charge, at the Civil Law 10 Self-Help Center at the Regional Justice Center, 200 Lewis Avenue, Las Vegas, Nevada, and on the center's website at www.civillawselfhelpcenter.org. 11 12 If you fail to respond, the Plaintiff can request your default. The court can then enter 13 judgment against you for the relief demanded by the Plaintiff in the complaint, which could result 14 in money or property being taken from you or some other relief requested in Plaintiff's complaint. 15 If you intend to seek an attorney's advice, do it quickly so that your response can be filed 16 on time. STEVEN D. GRIERSON, CLERK OF COURT 17 18 19 Deputy Clerk By: Regional Justice Center 20 200 Lewis Avenue 21 Las Vegas, NV 89155 Issued at the request of: 2.2. Demond Palmer THE VIEIRA FIRM 23 By: <u>/s/ Andréa L. Vieira</u> 24 ANDRÉA L. VIEIRA, ESQ. 25 Nevada Bar No. 15667 3100 W. Charleston Blvd., Ste. 200 26 Las Vegas, Nevada 89102 Attorney for Plaintiff 27

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Note: When service is by publication, add a brief summary of the claims asserted, the relief sought, and include any special statutory requirements. This summary should have been proposed through a Motion Seeking Publication and approved through an Order for Service by Publication. See Nevada Rule of Civil Procedure 4.4(c).

5/24/2022

Date

			Job # <u>7148019</u> Ref #
	Affidav	it of Process Server	
In The Di	strict Court for the 8	th Judicial District of Nevard in and for Clark County	
		(NAME OF COURT)	
Michele Brown, an individual	VS Ze	eltiq Aesthetics, Inc., a Delaware corporation, et al	A-22-848890-C
PLAINTIFF/PETITIONER		DEFENDANT/RESPONDENT	CASE NUMBER
within the boundaries of the state who	ere service was effec	that I am over the age of 18 years and not a party to ted, I was authorized to perform said service.	o this action, and that
Service: I served		Zeltiq Aesthetics, Inc. AME OF PERSON / ENTITY BEING SERVED	
	N	AME OF PERSON / ENTITY BEING SERVED	
with (list documents) Amended Summo	ons; and Amended C	omplaint (Received May 26, 2022 at 10:49am EDT)	
by leaving with	Curt Swelt:	z, Account Manager authorized to accept service	
		NAME/RELATIONSHIP/TITLE	
Service Address: <u>Corporate Creation</u>	s Network, Inc., Regi	stered Agent 3411 Silverside Rd., # 104 Tatnall Buildir	ng, Wilmington, DE 19810
On	Tue, May 31 2022	AT	01:50 PM
	DATE		TIME
Thereafter copies of the documents we	re mailed by prepaid	l, first class mail on	
·		DATE	
from			
fromCITY	STATE	ZIP	
Manner of Service:			
Personal: By personally delivering	copies to the person	being served.	
Substituted at Residence: By leavir	ng copies at the dwel	lling house or usual place of abode of the person bei	ng served with a member
of the household over the age of 18 and	d explaining the gen	eral nature of the papers.	
Substituted at Business: By leaving apparently in charge thereof.	g, during office hours	s, copies at the office of the nerson/entity being serve	
apparentivini charge thereor.		y espice at and office of the personnertary being serve	ed with the person
	g copies to the perso		ed with the person
X Corporate: By personally delivering			ed with the person
X Corporate: By personally delivering	spicuous manner to	on named above the front door of the person/entity being served.	ed with the person
X Corporate: By personally delivering Posting: By posting copies in a con Inquired If subject was a member of	spicuous manner to of the U.S. Military ar nquiry and diligent a	on named above. the front door of the person/entity being served. nd was informed they are not. ttempts at the address(es) listed above, I have been to	
X Corporate: By personally delivering Posting: By posting copies in a con Inquired if subject was a member of Non-Service: After due search, careful in upon the person/entity being served be	spicuous manner to of the U.S. Military ar nquiry and diligent a cause of the followin	on named above. the front door of the person/entity being served. nd was informed they are not. ttempts at the address(es) listed above, I have been to	inable to effect process
X Corporate: By personally delivering Posting: By posting copies in a con Inquired if subject was a member of Non-Service: After due search, careful in upon the person/entity being served be Unknown at Address Moved, Address Does Not Exist Other	spicuous manner to of the U.S. Military ar nquiry and diligent a ccause of the followin  Left no Forwarding	on named above. the front door of the person/entity being served. nd was informed they are not. ttempts at the address(es) listed above, I have been to ng reason(s):	inable to effect process ve in Timely Fashion
X Corporate: By personally delivering Posting: By posting copies in a con Inquired if subject was a member of Non-Service: After due search, careful in upon the person/entity being served be Unknown at Address Moved, Address Does Not Exist Other	spicuous manner to of the U.S. Military ar nquiry and diligent a ccause of the followin  Left no Forwarding	on named above. the front door of the person/entity being served, and was informed they are not.  Ittempts at the address(es) listed above, I have been using reason(s):  Service Cancelled by Litigant Unable to Serv	inable to effect process ve in Timely Fashion
Corporate: By personally delivering Posting: By posting copies in a con Inquired if subject was a member of Non-Service: After due search, careful in upon the person/entity being served be Unknown at Address Moved, Address Does Not Exist Other Description: Age 60 Sex Male	spicuous manner to of the U.S. Military ar nquiry and diligent a ccause of the followin  Left no Forwarding	on named above. the front door of the person/entity being served, and was informed they are not.  Ittempts at the address(es) listed above, I have been using reason(s):  Service Cancelled by Litigant Unable to Serv	unable to effect process  ve in Timely Fashion  d Glasses

SIGNATURE OF NOTARY RUBLYC NOTARY PUBLIC for the State of Delaware

KIMBERLY J. RYAN NOTARY PUBLIC STATE OF DELAWARE My Commission Expires March 31, 2024

Subscribed and sworn before me a Notary Public of the State

of Delaware on June 01, 2022 (Date)

The State of Nevada, its political subdivisions, agencies, officers, employees, board members, commission members, and legislators each have 45 days after service of this Summons within which to file a response to Plaintiff's complaint.

1 on you (not counting the day of service), you must: 2 3 4 other response) to Plaintiff's complaint. 5 2. 6 7 3. 8 name and address is shown below. 9 10 11 12 13 14 15 16 on time. 17 18 19 By: Deputy Clerk 20 21 Issued at the request of: 22 THE VIEIRA FIRM 23 By: \_/s/ Andréa L. Vieira 24 ANDRÉA L. VIEIRA, ESQ. 25 Nevada Bar No. 15667 3100 W. Charleston Blvd., Ste. 200 26 Las Vegas, Nevada 89102 27

File with the Clerk of the Court, whose address is shown below, a formal written response (typically a legal document called an "answer," but potentially some

- Pay the required filing fee to the court, or file an Application to Proceed In Forma Pauperis and request a waiver of the filing fee.
- Serve (by mail or hand delivery) a copy of your response upon the Plaintiff whose

Information and forms to assist you are available, free of charge, at the Civil Law Self-Help Center at the Regional Justice Center, 200 Lewis Avenue, Las Vegas, Nevada, and on the center's website at www.civillawselfhelpcenter.org.

If you fail to respond, the Plaintiff can request your default. The court can then enter judgment against you for the relief demanded by the Plaintiff in the complaint, which could result in money or property being taken from you or some other relief requested in Plaintiff's complaint.

If you intend to seek an attorney's advice, do it quickly so that your response can be filed

#### STEVEN D. GRIERSON, CLERK OF COURT

5/24/2022

Date

Regional Justice Center 200 Lewis Avenue Las Vegas, NV 89155

Demond Palmer

Attorney for Plaintiff

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Note: When service is by publication, add a brief summary of the claims asserted, the relief sought, and include any special statutory requirements. This summary should have been proposed through a Motion Seeking Publication and approved through an Order for Service by Publication. See Nevada Rule of Civil Procedure 4.4(c).

#### AFFIDAVIT OF SERVICE

Case:	Court:	County:	Job:
A-22-848890-C	Eighth Judicial District Court	Clark, NV	7149892 (A-22-848890-C)
Plaintiff / Petitioner:		Defendant / Respondent:	
Michele Brown		Zeltiq Aesthetics, Inc.; et al	
Received by: Clark County Proce	ess Service, LLC	For: The Vieira Firm	
To be served upon Orange Twist, LLC	: c/o Registered Agent Edwardo Saladana		

I, Phil Gervasi, being duly sworn, depose and say: I am over the age of 18 years and not a party to this action, and that within the boundaries of the state where service was effected, I was authorized by law to make service of the documents and informed said person of the contents herein

Recipient Name / Address: Kevin Parker for Orange Twist, LLC c/o Registered Agent Edwardo Saladana, URS Agents LLC: 4625 W Nevso Dr

Ste 2 & 3, Las Vegas, NV 89103

Manner of Service:

Registered Agent, May 27, 2022, 10:09 am PDT

Documents:

Amended Summons; First Amended Complaint

#### Additional Comments:

1) Successful Attempt: May 27, 2022, 10:09 am PDT at URS Agents LLC: 4625 W Nevso Dr Ste 2 & 3, Las Vegas, NV 89103 received by Kevin Parker for Orange Twist, LLC c/o Registered Agent Edwardo Saladana. Age: 40; Ethnicity: Caucasian; Gender: Male; Height: 5'8"; Relationship: Office manager;

05/27/2022

Phil Gervasi R-2018-01519 Date

Clark County Process Service, LLC 2500 Chandler Ave #4 Las Vegas, NV 89120

702-491-7799

**EXHIBIT 2** 

**LLC-12** 

21-F76870

## FII FD

In the office of the Secretary of State of the State of California

NOV 02, 2021

**IMPORTANT** — Read instructions before completing this form.

Filing Fee - \$20.00

Copy Fees - First page \$1.00; each attachment page \$0.50; Certification Fee - \$5.00 plus copy fees

This Space For Office Use Only

<ol> <li>Limited Liability Company Name (Enter the exact name)</li> </ol>	ne of the LLC. If you registered in California using an alternate name, see instructions.)
ORANGE TWIST LLC	
2. 12-Digit Secretary of State File Number	3. State, Foreign Country or Place of Organization (only if formed outside of California)
202028010101	NEVADA

NEVADA

4. Business Addresses a. Street Address of Principal Office - Do not list a P.O. Box City (no abbreviations) State Zip Code 730 South Allied Way, Suite C El Segundo 90245 CA b. Mailing Address of LLC, if different than item 4a City (no abbreviations) Zip Code State 730 South Allied Way, Suite C El Segundo CA 90245 c. Street Address of California Office, if Item 4a is not in California - Do not list a P.O. Box City (no abbreviations) Zip Code State 730 South Allied Way, Suite C El Segundo CA 90245

5. Manager(s) or Member(s)

If no managers have been appointed or elected, provide the name and address of each member. At least one name and address must be listed. If the manager/member is an individual, complete Items 5a and 5c (leave Item 5b blank). If the manager/member is an entity, complete Items 5b and 5c (leave Item 5a blank). Note: The LLC cannot serve as its own manager or member. If the LLC has additional managers/members, enter the name(s) and addresses on Form LLC-12A (see instructions).

a. First Name, if an individual - Do not complete Item 5b Clint	Middle Name	Last Name Carnell		Suffix
b. Entity Name - Do not complete Item 5a	1	•		·
c. Address 730 South Allied Way, Suite C	City (no abbreviations) El Segundo		State Zip Code CA 90245	

6. Service of Process (Must provide either Individual OR Corporation.)

INDIVIDUAL - Complete Items 6a and 6b only. Must include agent's full name and California street address.

a. Callfornia Agent's First Name (if agent is not a corporation)  Brittany	Middle Name	Last Name Slater			Suffix
b. Street Address (if agent is not a corporation) - Do not enter a P.O. Box 730 South Allied Way, Suite C	City (no abbreviations) El Segundo		State CA	Zip Co 902	

CORPORATION - Complete Item 6c only. Only include the name of the registered agent Corporation

c. California Registered Corporate Agent's Name (if agent is a corporation) - Do not complete Item 6a or 6b	

7. Type of Business

a. Describe the type of business or services of the Limited Liability Company Management Services

8. Chief Executive Officer, if elected or appointed

a. First Name	Middle Name	Last Name			Suffix
b, Address	City (no abbreviations)		State	Zip Co	ode

9. The Information contained herein, including any attachments, is true and correct.

11/02/2021	Allison Shipley	Paralegal	
Date	Type or Print Name of Person Completing the Form	Title	Signature
Return Address (Optio	nal) (For communication from the Secretary of State related to this do	cument, or if purchasing	

person or company and the mailing address. This information will become public when filed. SEE INSTRUCTIONS BEFORE COMPLETING.)

Name: Company: Address:

City/State/Zip:

**EXHIBIT 3** 

	SATION						
	Entity Name:	ORANGE TWIST LLC		Entity Number:	E0181492019-0		
	Entity Type:	Domestic Limited-Liability Company (86)		Entity Status;	Active		
	Formation Date:	04/18/2019		NV Business ID:	NV20191298845		
•	Termination Date:	Perpetual		Annual Report Due Date:	4/30/2023		
	Series LLC:	£1		Restricted LLC:	1.3		
	***		***************************************	***************************************	***************************************		
ILING HISTORY D	ETAILS						
lle Date	Effective Date	Filing Number	Document Type	Ал	nendment Type	Source	View
4/22/2022	04/22/2022	20222270455	Annual List			External	<u>e</u> i
4/29/2021	04/29/2021	20211423505	Annual List			External	e
1/28/2021	01/28/2021	20211197197	Annual List			External	Ø
4/18/2019	04/18/2019	20190170192-12	Initial List			External	Ø
4/18/2019	04/18/2019	20190170191-01	Articles of Organization			External	roi
Page 1 of 1, records 1	to 5 of 5						
II ING DATE SMA	PSHOT AS OF: 04/22/202	·····					······
TENO DATE SNA	-31101 M3 OF, 04/22/202						***************************************
Business Deta	ls Name Changes	Principal Office Registered Agent	Officer Information	Shares			
Date	Title	Name	Attention	Address1/Address2/City/State/Zip/Country			
	Manager	Kenneth Kay		2220 Avenue of the Stars, #2203, Los Angeles, CA, 900	067, USA		
01/28/2021	Manager	JARED SMITH		730 South Allied Way, Suite C, El Segundo, CA, 90245,	USA		
01/28/2021 01/28/2021		CLINT CARNELL		730 South Allied Way, Suite C, El Segundo, CA, 90245,	USA		
01/28/2021		Paul Gainer		730 South Allied Way, Suite C, El Segundo, CA, 90245,	USA		

Back Return to Search Return to Results